Supreme Court, U.S.
FILED

(2)

931431 MAR - 7 1994

No. OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1993

MEDICAL ENGINEERING CORPORATION,
Petitioner,

v.

AMERICAN MEDICAL SYSTEMS, INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

APPENDIX TO THE PETITION FOR A WRIT OF CERTIORARI

MARK T. BANNER
Counsel of Record
JERRY A. RIEDINGER
MARC S. COOPERMAN
A. BLAIR HUGHES
ALLEGRETTI & WITCOFF, LTD.
10 South Wacker Drive
Suite 3000
Chicago, Illinois 60606
(312) 715-1000
Counsel for Petitioner

March 7, 1994

Midwest Law Printing Co., Chicago 60611, (312) 321-0220

120P

INDEX TO APPENDIX

	App. Page
Opinion of the United States Court of Appeals for the Federal Circuit, filed October 4, 1993	1
Opinion of the United States District Court for the Eastern District of Wisconsin, filed June 25, 1992 .	37
Order of the United States Court of Appeals for the Federal Circuit Denying Rehearing, and Declining Rehearing in Banc, filed December 6, 1993 ...	117

IN THE

Supreme Court of the United States

OCTOBER TERM, 1993

MEDICAL ENGINEERING CORPORATION,

Petitioner,

v.

AMERICAN MEDICAL SYSTEMS, INC.,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

---

APPENDIX TO THE PETITION FOR A WRIT OF CERTIORARI

App. 1

Nos. 92-1538, 92-1555

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

AMERICAN MEDICAL SYSTEMS, INC.,

Plaintiff/Cross-Appellant,

v.

MEDICAL ENGINEERING CORPORATION,

Defendant-Appellant.

October 4, 1993

OPINION:

Before NIES, Chief Judge, MICHEL and RADER, Circuit Judges.

MICHEL, Circuit Judge.

American Medical Systems, Inc. (AMS)[1] brought suit in the United States District Court for the Eastern District of Wisconsin against Medical Engineering Corporation (MEC)[2] for willful infringement of United States Patent No. 4,597,765, issued to Klatt (the '765 patent).

---

[1] AMS is a wholly-owned subsidiary of Pfizer, Inc.

[2] MEC was originally an independent company, but during the course of this litigation it became a wholly-owned subsidiary of Bristol-Myers Company (now Bristol-Myers Squibb Corporation) in 1982.

MEC counterclaimed for declaratory judgment of invalidity and noninfringement, for an alleged breach of warranty, and for intentional, negligent and fraudulent misrepresentation by AMS.

After a bench trial, the district court issued its Decision and Order, No. 87-C-1236(JPS),[3] on June 25, 1992, rejecting each of MEC's counterclaims and holding that the '765 patent was not invalid and was infringed. The court further found that MEC's infringement was willful and that AMS was entitled to an award of enhanced damages of 1.5 times its proven lost profits and reasonable royalties. The court limited AMS's recoverable damages to those incurred after the filing date of the lawsuit, however, due to AMS's initial failure to mark its patented articles under 35 U.S.C. § 287(a) (1988). On September 1, 1992, the district court entered judgment in accord with its decision and permanently enjoined MEC from any further infringement of the '765 patent.

On appeal, MEC concedes validity and infringement, but challenges the district court's finding of willfulness and its award of enhanced damages. MEC also argues error in the denial of its counterclaim for breach of warranty and additionally alleges a violation of its Seventh Amendment right to a jury trial.[4] AMS cross-appeals the district court's limitation of its recoverable damages under 35 U.S.C. § 287(a).

---

[3] The district court opinion is reported at 794 F. Supp. 1370, 26 USPQ2d (BNA) 1081 (E.D. Wis. 1992).

[4] MEC does not appeal the district court's ruling on its misrepresentation counterclaims.

Because the district court's finding of willfulness is not clearly erroneous, we affirm the court's finding on this aspect. Because no abuse of discretion has been shown, we also affirm the court's enhancement of the actual damages by 1.5 times. Finding no error, we also affirm the district court's holding that there was no breach of warranty. Furthermore, we hold that MEC's alleged violation of its Seventh Amendment right to a jury trial is without merit. On AMS's cross-appeal, however, because the district court improperly construed 35 U.S.C. § 287(a) in limiting AMS's recoverable damages to those incurred after the suit was filed, we reverse and remand to the district court for a new determination of damages consistent with this decision.

BACKGROUND

1. History of Competition Between AMS and MEC

AMS and MEC were vigorous competitors in the area of penile prostheses.[5] Each company had its own commercial version of a fluid-filled prosthetic device. AMS's prosthesis was called the "Hydroflex" and MEC's equivalent device was the "Flexi-Flate." Both devices were initially sold unfilled in a "dry pack" configuration.

AMS and MEC were previously involved in two interference proceedings and one arbitration concerning this prosthesis technology. All of these prior actions were settled by agreement of the parties.

---

[5] MEC states that it abandoned the penile prosthesis market in the summer of 1991.

One of the interference actions, Interference No. 100,779 (the '779 interference), was settled by an agreement known as the "Hakky agreement."[6] All of the counts of the '779 interference were directed solely to the prosthetic devices themselves.

The Hakky agreement contained a warranty provision which was set out in two paragraphs of the settlement agreement as follows:

> 17.7. AMS and MEC each represent that their respective current technical disclosures to each other are accurate and complete with respect to the patent issues in the '779 interference.
>
> 17.8. AMS and MEC each warrant that there are no other issued patents, nor any pending applications for letters patent, reissue, continuation, continuation-in-part, or divisions with respect to any device disclosed to the warranting party by the other party which would result in any infringement or other potential litigation issue.

The Hakky agreement was signed by both parties in March of 1985.[7] The disclosures made by both parties

---

[6] At trial, MEC also referred to the settlement agreement from the other interference, (the Finney agreement), and the arbitration agreement between the parties. MEC's arguments on appeal do not rely on these agreements; accordingly, these agreements will not be addressed further.

[7] The application for the '765 patent was pending at the time this agreement was signed by the parties. The '765 patent is

(continued...)

pursuant to the Hakky agreement were limited to technology involving the actual devices. At the time of this agreement, neither party discussed nor implicated matters beyond the actual devices themselves, such as the concept of pre-filling the devices during manufacture, sterilization of the devices, or packaging of the devices for implantors.

2. The Patent in Suit

The present appeal involves AMS's '765 patent, which claims an apparatus and method for packaging a fluid-containing penile prosthesis in a pre-filled, sterile state. The prosthesis itself comprises a hydraulic, inflatable, fluid-permeable silicone cylinder with a fluid reservoir and pump contained in the cylinder, which is self-contained such that the entire prosthesis is implanted into the penis. Both the Hydroflex and the Flexi-Flate are this type of device. The packaging comprises a sterile, fluid-filled inner package that holds the pre-filled prosthesis and a non-sterile outer package that contains the inner package in a sterile state. This packaging configuration is referred to in the industry as the "wet pack."

AMS filed its application claiming the combination of a pre-filled prosthesis stored in the double layer packaging on December 27, 1984. The '765 patent issued from this application on July 1, 1986. Claims 1-12 and 21-24

---

[7] (...continued)
unrelated to the '779 interference, other than by MEC's contentions that it was required to be disclosed pursuant to the warranty provisions of the Hakky agreement.

of the '765 patent are directed to the apparatus comprising the pre-filled and pre-sterilized packaged prosthesis. Claims 14-15 and 18-20 of the '765 patent are directed to the method of making and sterilizing a packaged pre-filled and pre-sterilized prosthesis.

The prior art unfilled prosthesis, such as the dry-pack Hydroflex or dry-pack Flexi-Flate, required filling in the operating room prior to implantation. This was undesirable because it increased the operating time required to implant the prosthesis and could lead to certain problems due to improper filling or leaking.

The subject matter of the '765 patent solved the problems of the prior art dry-pack configuration devices by pre-filling the prosthesis with a saline solution and immersing it in a foil pouch filled with a saline solution having the same osmotic properties as the solution within the prosthesis. This allowed the liquid level within the device to be maintained at a precise level while in storage prior to implantation. This inner foil pouch was then sterilized and stored inside an outer non-sterile container. The two layer packaging configuration allowed for a non-sterile nurse to open the non-sterile outer package and present the sterile inner package containing the pre-filled prosthesis to a sterile nurse to open in the operating field. Because of these asserted advantages, there was a much greater demand in the market for a pre-filled, pre-sterilized prosthesis over an unfilled device.

3. MEC's Infringement

MEC began to work on the problem of marketing a pre-filled, sterilized packaged version of its Flexi-Flate

prosthesis in early 1984. MEC's original packaging concept involved placing the pre-filled prosthesis in a rigid vapor impermeable tube containing saline of the same osmolarity as that within the device. The rigid tube was then enclosed in a slightly larger tube or pouch. MEC also attempted reversing the relationship of the tube and the pouch. None of these attempts to design a pre-filled packaged prosthesis proved to be successful, however, due to problems with leaking and sterilization.

In May of 1985, MEC personnel saw AMS's pre-filled, sterilized Hydroflex prosthesis in the wet pack packaging configuration at the annual American Urological Association trade show. The AMS package at the trade-show was not marked with any patent pending notice, and no representations were made at that time that any patent applications had been filed. MEC abandoned its previous packaging configurations after it obtained a sample of the Hydroflex device and packaging, which it referred to in creating its own double foil pouch wet pack packaging. MEC then introduced its own wet pack "Flexi-Flate" prosthesis in the market in May 1985. MEC also filed a patent application on its pre-filled product and package, but the application was later abandoned.

MEC became aware of the '765 patent shortly after it issued in late July 1986, through the efforts of its in-house patent counsel, Stuart Krieger.[8] AMS's patent counsel, James Elacqua, also called Krieger twice in August 1986, to advise MEC of the existence of the '765

---

[8] Krieger was actually employed by Bristol-Myers, of which MEC is a subsidiary. Krieger was responsible for MEC's patent matters and acted as an in-house counsel for MEC.

patent. No accusation of infringement was made by AMS at that time, however. Krieger immediately contacted MEC's vice president for scientific affairs, Garry Carter, to advise him of the patent. Krieger also testified that he authorized performance of several patent validity searches on the '765 patent. These opinions were withheld at trial, however. At the end of August or the beginning of September of 1986, Krieger informed MEC's president, Robert Helbling, in an oral opinion that the '765 patent was invalid for obviousness and that MEC's wet pack Flexi-Flate fell literally within the scope of the '765 patent claims.

Shortly after learning of AMS's '765 patent, MEC began work on an alternative packaging configuration for its pre-filled device, known as the "vacuum pack." MEC did not begin selling the vacuum pack in the market until about January 1988. Even after development of the vacuum pack, MEC continued to ship its remaining inventory of the wet pack Flexi-Flate throughout the remainder of 1988.

4. The '765 Patent Litigation

AMS filed a complaint on October 28, 1987, accusing MEC of willful infringement of claims 1-12, 14-15, 18-20 and 21-24 of the '765 patent. The original complaint contained a jury demand and the case was docketed as a jury case. Although counsel for AMS informed counsel for MEC that the complaint had been filed, the complaint was not served at the time of filing. Settlement discussions ensued between the parties.

Meanwhile, in early November 1987, MEC contacted Mrs. Jamie Smith of Allegretti & Witcoff to conduct a validity evaluation of the patent. Smith provided an oral opinion to Krieger in December 1987 or January 1988, concluding that the '765 patent was invalid for obviousness, and that some claims were arguably anticipated. Smith put her opinion in writing, at Krieger's request, on February 24, 1988.

The settlement discussions between the parties were unsuccessful. In February 1988, AMS filed and served an amended complaint which differed from the original complaint only in that it did not contain a jury demand. MEC filed its Answer to the Amended Complaint on June 1, 1988, and later filed an Amended Answer and Counterclaims to the Amended Complaint on February 1, 1989. MEC's counterclaims included a request for declaratory judgment of invalidity and noninfringement as well as a breach of warranty claim and three counterclaims charging AMS with intentional, negligent, and fraudulent misrepresentation. The pleading did not mention a jury trial, however.

MEC's counterclaims for breach of warranty and for tortious misrepresentation were based primarily on the Hakky settlement agreement. MEC alleged that under the terms of the warranty provisions of the Hakky agreement, AMS "warranted that there [were] no other . . . pending applications for letters patent . . . with respect to any device disclosed to [MEC] . . . which would result in any infringement or other potential litigation." [¶ 17.8 Hakky agrmt.] The Klatt application, which matured into the '765 patent, was pending during the final negotiations of the Hakky agreement. Therefore, MEC argues

that AMS's failure to disclose the pending Klatt application was a breach of warranty because AMS knew that it was likely to result in litigation between the parties. MEC further alleged, in three additional counterclaims, that the "breach of warranty" resulting from AMS's nondisclosure amounted to a tortious misrepresentation.

In May of 1991, MEC moved for a jury trial relying on the jury trial demand in the original complaint. The district court denied MEC's motion on the basis that the original complaint was never served as required by Rule 38, Fed. R. Civ. P, and that therefore there had never been a proper demand for a jury trial. The court also noted that the issue of a jury trial was never raised in the pretrial conference in July of 1990. The district court concluded that the right to a jury trial had been waived.

5. The District Court Decision

MEC stipulated that its Flexi-Flate prosthesis would infringe the '765 patent, if valid, but argued at trial that the '765 patent was invalid for obviousness. The district court held that the '765 patent was not invalid for obviousness and therefore, in accord with MEC's stipulation, found infringement by MEC's wet pack Flexi-Flate. The district court further found that MEC willfully infringed the '765 patent and awarded enhanced damages of 1.5 times AMS's proven lost profits and reasonable royalties.

On MEC's warranty counterclaim, the district court found that the Hakky agreement was unambiguous and required the parties to disclose only those patents and applications implicated by the limited current technical

disclosures relating to the interference. Therefore, AMS was not required to disclose the '765 patent application because it did not relate to the interference. Consequently, the district court concluded that AMS did not breach any warranty in failing to disclose the '765 patent application to MEC as part of the interference settlement agreement. Likewise, with respect to MEC's misrepresentation counterclaims, the district court found that AMS made no misrepresentation of fact in not disclosing the application leading to the '765 patent to MEC because it "was not within the scope of the interference and consequently was not required to be revealed in order to comply with the warranty." *American Medical Sys., Inc. v. Medical Eng'g Corp.*, 794 F. Supp. 1370, 1404, 26 USPQ2d (BNA) 1081, 1105 (E.D. Wis. 1992).

As damages, AMS asserted entitlement to lost profits for the period of July 1, 1986 (the issue date of the '765 patent), through December 1987, after which MEC's non-infringing "vacuum pack" Flexi-Flate entered the market. From January 1988 on, AMS claimed entitlement to a reasonable royalty for MEC's continued shipping of its remaining inventory of the wet pack Flexi-Flates.

In awarding damages, the district court noted that AMS did not begin to mark its Hydroflex device until two months after the patent issued and that AMS did not begin shipping those marked devices until October 15, 1986. From this, the district court concluded that more than a *de minimis* number of devices was shipped without any patent marking pursuant to 35 U.S.C. § 287(a). Accordingly, the district court held that AMS was only entitled to damages from the date that it gave MEC actual notice of infringement. The district court further

found that actual notice was not given until the present lawsuit was filed on October 28, 1987. Therefore, the district court found that AMS was entitled to lost profits for the period of October 28, 1987 through December 1988, in the amount of $906,806.00, and to a reasonable royalty for the period of January 1988 to December 1988 in the amount of $46,264.24. This equals a total amount of $953.070.24 in lost profits and reasonable royalties, multiplied by 1.5, resulting in total damages of $1,429,605.30.

MEC appeals the district court's award of enhanced damages and challenges the finding of willfulness. Additionally, MEC argues that the district court erroneously construed the warranty provision of the Hakky agreement. Finally, MEC argues that the district court wrongfully denied its request for a jury trial under the Seventh Amendment.

AMS cross-appeals the district court's limitation of recoverable damages because of its initial failure to mark its patented product pursuant to 35 U.S.C. § 287(a).

ANALYSIS

I.

A. Willfulness

MEC argues that the district court applied the wrong legal standard in determining willfulness and, therefore, this finding should be overturned. A finding of willfulness requires the factfinder to find that clear and convincing evidence shows "that the infringer acted in disregard of the patent . . . [and] had no reasonable basis

for believing it had a right to do the acts." *Stickle v. Heublein, Inc.*, 716 F.2d 1550, 1565, 219 USPQ (BNA) 377, 378 (Fed. Cir. 1983). This is a factual determination to be made after consideration of the totality of the circumstances. *Studiengesellschaft Kohle, m.b.H. v. Dart Indus., Inc.*, 862 F.2d 1564, 1573, 9 USPQ2d (BNA) 1273, 1282 (Fed. Cir. 1988). In making a determination of willfulness, the court is also required to consider mitigating or ameliorating factors. *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 826, 23 USPQ2d (BNA) 1426, 1435 (Fed. Cir. 1992). We review the court's determination of willfulness under a clearly erroneous standard. *Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1580, 24 USPQ2d (BNA) 1321, 1338 (Fed. Cir. 1992).

MEC contests the willfulness finding by relying on the district court's statement that "[b]asically, there was a lack of evidence of good faith rather than explicit evidence of bad faith." 794 F. Supp. at 1399, 26 USPQ2d (BNA) at 1101. Based on this language, MEC argues that the district court applied the wrong legal standard, erroneously requiring MEC to prove "good faith" to avoid a finding of willfulness and a possible award of enhanced damages.

We reject MEC's contention that the district court applied the wrong legal standard. The language cited and relied on by MEC that indicates that the district court considered MEC's "lack of good faith" appears in a section of the opinion discussing the district court's denial of attorney fees. Therefore, it is not conclusive of the willfulness standard applied by the district court. In any event, in the section of the opinion dealing specifical-

ly with willfulness, the district court clearly set out the correct legal standard. *Id.* at 1395, 26 USPQ2d (BNA) at 1098. The context of the district court's specific discussion of willfulness clearly indicates that it applied the correct legal standard. Therefore, it is clear that MEC's argument is based solely on one passing statement taken out of context, and provides no grounds for reversal. *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 895 F.2d 1403, 1406, 13 USPQ2d (BNA) 1871, 1874 (Fed. Cir. 1990) ("[J]udgments, not words, are appealable."); *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 718, 223 USPQ (BNA) 1264, 1272 (Fed. Cir. 1984) (this court reviews "final decisions, not passing comments").

Moreover, the district court considered the totality of the circumstances in reaching its determination that MEC willfully infringed the '765 patent. The district court found that MEC knew of the '765 patent shortly after it issued in July of 1986, through the efforts of its in-house patent counsel, Krieger. Krieger informed MEC that its Flexi-Flate product infringed the '765 patent. The district court also found that MEC had no reasonable good faith belief to justify its continued infringement because Krieger's oral invalidity opinion lacked credibility and because the Smith opinion, though credible, came too late to be reasonably relied upon because "it was not rendered until MEC had been infringing the ['765] patent for almost twenty months." 794 F. Supp. at 1398, 26 USPQ2d (BNA) at 1101. Moreover, the district court found that "[t]he [Smith] opinion was written after MEC had stopped making the wet pack, and after suit had been filed," and further, that "Mr. Helbling [MEC's presi-

dent] had no knowledge of the Smith opinion in 1986-87 and testified that he relied only on Mr. Krieger's [oral] opinion." *Id.*, 794 F. Supp. at 1398, 226 USPQ2d at 1101. MEC does not challenge these findings, which we thus have no basis to overturn as clearly erroneous. Furthermore, MEC chose to withhold all of the documentary evidence of prior searches and outside counsel opinions upon which Krieger allegedly relied in rendering his oral opinion, from which the district court properly drew a negative inference. *Fromson v. Western Litho Plate & Supply Co.*, 853 F.2d 1568, 1572-73, 7 USPQ2d (BNA) 1606, 1611 (Fed. Cir. 1988) ("Where the infringer fails to introduce an exculpatory opinion of counsel at trial, a court must be free to infer that either no opinion was obtained or, if an opinion were obtained, it was contrary to the infringer's desire to initiate or continue its use of the patentee's invention."). Finally, the court found that MEC deliberately copied the AMS package design in developing its infringing dual pouch Flexi-Flate wet pack product. MEC has not shown these fact findings to be clearly erroneous.

Despite these findings, MEC argues that the district court erred in reaching its ultimate determination of willfulness because it allegedly ignored certain mitigating or ameliorating factors. According to MEC, these mitigating factors include the fact that it began designing a non-infringing alternative to the wet pack Flexi-Flate, the vacuum pack, soon after learning of the patent along with AMS's delay for an extended period of time before giving any notice of infringement to MEC. Therefore, MEC asserts that, considering these factors, the district court's determination of willfulness is clearly erroneous.

This argument also fails. The fact that these factors were not specifically mentioned in the district court's discussion of willfulness does not support the conclusion that they were not considered. All of the factors raised by MEC were discussed by the district court at some point in its opinion. Furthermore, none of the factors mentioned by MEC are inconsistent with a finding of willfulness. MEC's attempt to design a non-infringing alternative does not negate MEC's continuing sales of infringing devices during the redesign period. Nor does AMS's delay in filing suit negate the fact that MEC had actual knowledge of the '765 patent and had no reasonable basis upon which to rely in its continued infringement. Moreover, it is apparent that the district court took into account mitigating factors in determining the degree of willfulness, because it chose to award enhanced damages of only 1.5 times the total amount rather than awarding the maximum treble damages allowable under 35 U.S.C. § 284 (1988). An award of enhanced damages under section 284 is within the discretion of the district court and will not be overturned absent a clear showing of abuse of discretion. *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1547-48, 221 USPQ (BNA) 1, 8 (Fed. Cir. 1984).

Because MEC has failed to show any legal or factual error by the district court, we uphold the court's finding of willfulness. Additionally, we affirm the district court's award of enhanced damages because MEC has failed to show that the district court abused its discretion in this matter.

B. Breach of Warranty

On appeal, MEC also argues that the district court erred as a matter of law in construing the warranty agreement between AMS and MEC. The district court found that the warranty provision contained in paragraphs 17.7 and 17.8 of the Hakky agreement was unambiguous. The district court further found that the unambiguous language of the " 'warranty' in 17.8 requires the parties to disclose only those patents implicated by the limited 'current technical disclosures' referred to paragraph 17.7." 794 F. Supp. at 1401, 26 USPQ2d (BNA) at 1103. The district court then concluded that because the '765 patent did not relate to the '779 interference, its disclosure was not required and, therefore, AMS did not breach the warranty for failing to disclose the pending application. *Id.*, 26 USPQ2d (BNA) at 1103.

Contrary to its position at trial, MEC argues on appeal that the district court correctly held that the warranty provision of the Hakky agreement is unambiguous.[9] MEC also agrees with the district court that para-

---

[9] AMS argues that MEC waived its argument on appeal that the warranty provision was unambiguous, because at trial MEC took the contrary position that the warranty provision was ambiguous. *Braun, Inc. v. Dynamics Corp. of Am.*, 975 F.2d 815, 821, 24 USPQ2d (BNA) 1121, 1126 (Fed. Cir. 1992) (argument that failure to introduce empirical evidence precluded finding of design patent infringement waived where issue of sufficiency of evidence was not raised before district court); *Libertyville Datsun Sales, Inc. v. Nissan Motor Corp. in U.S.A.*, 776 F.2d 735, 737 (7th Cir. 1985) (argument based on amendment to agreement waived because not made at trial

(continued...)

graphs 17.7 and 17.8 are interrelated. However, MEC argues that the unambiguous language of the agreement is broader than the district court's interpretation. MEC argues that the district court's interpretation reads additional limitations into paragraph 17.8 by concluding that any required disclosure under the warranty must have some relation to the '779 interference. According to MEC, the plain language of paragraph 17.8 required AMS to disclose any patent or application which may result in any potential litigation with respect to the disclosed Flexi-Flate device. Therefore, MEC asserts that the Klatt application should have been disclosed under the warranty, because AMS should have reasonably known that it would result in potential litigation between the parties.

---

[9] (...continued)
even where general issue of interpretation of agreement and amendment was before district court).

The cases cited by AMS are distinguishable, however, because in those cases a party attempted to present arguments that were not actually considered by the district court. In this case, however, the precise issue of whether the warranty provision was ambiguous or unambiguous was put before the district court. Furthermore, the district court did actually determine that the agreement was unambiguous and interpreted the specific language of the agreement that is relied upon by MEC in its arguments on appeal as such as a matter of law. Therefore, even though MEC argued at trial that the warranty provision was ambiguous, it is not prevented from arguing on appeal that the district court's interpretation of the unambiguous language was incorrect as a matter of law because its arguments on appeal raise nothing that was not considered by the district court.

State law, in this case Wisconsin law, controls in matters of contract law and interpretation. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1241, 9 USPQ2d (BNA) 1913, 1924 (Fed. Cir.), *cert. denied*, 493 U.S. 853, 107 L. Ed. 2d 112, 110 S. Ct. 154 (1989); *Universal Gym Equip., Inc. v. ERWA Exercise Equip. Ltd.*, 827 F.2d 1542, 1550, 4 USPQ2d (BNA) 1035, 1040 (Fed. Cir. 1987). Interpretation of an unambiguous contract provision is a question of law which is subject to de novo review. *Lakeshore Commercial Fin. Corp. v. Drobac*, 107 Wis. 2d 445, 457, 319 N.W.2d 839, 843 (1982).

The warranty provision of paragraph 17.8 provides that each party warrants that there are no "pending applications . . . with respect to any device disclosed to the warranting party by the other party which would result in any infringement or other potential litigation issue." Looking at the plain language of these provisions, we conclude, as did the district court, that the "disclosure" referred to in paragraph 17.8 relates back to the "current technical disclosure . . . with respect to the patent issues in the '779 interference" specified by paragraph 17.7. Therefore, as a matter of law, the warranty only applies to those pending applications implicated by the devices that were disclosed relating to the patent issues of the '779 interference.

To interpret the warranty provision as MEC urges, i.e., that any application which could result in any potential litigation whatsoever with any disclosed device, reads the warranty provision out of context. The "disclosures" referred to in paragraphs 17.7 and 17.8 were made specifically with respect to the patent issues involved in the '779 interference. The district court found

that the subject matter of the '765 patent did not relate to "the patent issues in the '779 interference." 794 F. Supp. at 1401, 26 USPQ2d (BNA) at 1103. MEC does not contest this finding. Therefore, the '765 patent application was not required to be disclosed under paragraph 17.7. Moreover, the facts are undisputed that neither party disclosed anything relating to the pre-filling, pre-sterilizing or packaging of their respective devices which would have implicated the Klatt application, thereby requiring disclosure pursuant to paragraph 17.8. Hence, we conclude that the district court correctly determined that disclosure of the Klatt application was not required by the terms of the Hakky agreement and, consequently, that there was no breach of warranty.

C. Jury Trial

MEC argues that the district court erroneously deprived it of its Seventh Amendment right to a jury trial. The district court denied MEC's pretrial motion for a jury trial, ruling that the original complaint containing the jury demand had never been served as required by Rule 38(b), Fed. R. Civ. P.[10] MEC asserts, however, that

---

[10] Rule 38(b) provides in relevant part:

> (b) Demand. Any party may demand a trial by jury . . . by serving upon the other parties a demand therefor in writing at any time after the commencement of the action and not later than 10 days after the service of the last pleading directed to such issue. Such demand may be indorsed upon a pleading of the party.

Also relevant is Rule 38(d) which provides in relevant part:

(continued...)

the district court made a contrary "finding" in its opinion that the original complaint had been served. In its discussion of "hard ball litigation tactics" in the "attorney fees" section of its opinion, the district court stated that "AMS filed the original complaint in this matter in October 1987, but did not *serve* it, until December 1987." 794 F. Supp. at 1399, 26 USPQ2d (BNA) at 1102. Based on this one statement, MEC argues that the original complaint was served and that it never consented to withdrawal of the jury demand as required by Rule 39(a), Fed. R. Civ. P.[11] Therefore, MEC asks this court to vacate the district court's judgment and remand for a jury trial.

Once again, MEC is relying on a stray comment in the district court's opinion to try to create a basis for its argument. There is no indication in the record that the

---

[10] (...continued)

(d) Waiver. The failure of a party to serve a demand as required by this rule . . . constitutes a waiver by the party of trial by jury. A demand for trial by jury made as herein provided may not be withdrawn without the consent of the parties.

[11] Rule 39(a), Fed. R. Civ. P., provides in relevant part:

When trial by jury has been demanded as provided in Rule 38, . . . the trial of all issues so demanded shall be by jury, unless (1) the parties or their attorneys of record, by written stipulation filed with the court or by an oral stipulation made in open court and entered in the record, consent to trial by the court sitting without a jury or (2) the court upon motion or of its own initiative finds that a right of trial by jury of some or all of those issues does not exist under the Constitution or statutes of the United States.

jury trial issue was before the court at trial,[12] let alone that the court's statement was intended to be a "finding" contradictory to its earlier ruling on MEC's motion that the original complaint was not served. Judge Stadtmueller's earlier finding that no jury demand had been served is supported by the record evidence. In making his ruling, the judge noted that in the Rule 16 pretrial conference occurring over a year before MEC's jury trial motion, neither party indicated that it was seeking a jury trial. Additionally, the court noted that in an earlier deposition, MEC's counsel, Mr. Banner, acknowledged that he was "not suggesting anything with regard to the matter of a jury trial." The court further noted that there was nothing in the record to establish that the original complaint had been served. The district court therefore concluded that "the matter of a jury trial was long ago waived." We repeat our earlier caution that this court reviews decisions, not statements in opinions. *Lindemann*, 895 F.2d at 1406, 13 USPQ2d (BNA) at 1874. We conclude that this passing statement does not constitute a contrary "finding" by the district court.

In addition, we note that the authority relied on by MEC to establish entitlement to a jury trial, *Thomson v. Jones*, 102 F.R.D. 619 (N.D. Ill. 1984), is inapposite. In *Thomson*, not only was the original complaint with the jury demand actually served on defendants, but the defendants' answer to the complaint demanded a jury trial. Here, by complete contrast, neither was the original com-

---

[12] The record shows that MEC failed to include the jury demand issue in the Rule 16 pretrial order or to otherwise raise the issue at trial.

plaint with the jury demand served nor was a jury demanded in the answer or amended answer, the latter of which was filed almost two years before the motion for a jury trial.

We conclude that MEC's argument is without merit.

II.

A. Patent Marking

AMS cross-appeals the district court's limitation of its recoverable damages to the period after the filing date of this lawsuit for failure to mark under 35 U.S.C. § 287(a),[13] claiming that the district court erroneously construed the statute. Statutory construction is a legal question which we review *de novo*. *Hoechst Aktiengesellschaft v. Quigg*, 917 F.2d 522, 526, 16 USPQ2d (BNA) 1549, 1552 (Fed. Cir. 1990).

---

[13] 35 U.S.C. § 287(a) provides:

> Patentees, and persons making or selling any patented article for or under them, may give notice to the public that the same is patented, either by fixing thereon the word "patent" or the abbreviation "pat.", together with the number of the patent, or when from the character of the article, this can not be done, by fixing to it, or to the package wherein one or more of them is contained, a label containing a like notice. In the event of failure so to mark, no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for the infringement occurring after such notice.

The district court found, and the parties do not dispute the following facts. The '765 patent issued on July 1, 1986. Prior to issuance of the '765 patent, AMS had already shipped 8,556 unmarked prostheses. 794 F. Supp. at 1392, 26 USPQ2d (BNA) at 1095 . AMS did not begin marking its product until about two months after issuance of the '765 patent, and did not begin shipping its marked products until October 15, 1986, three and one-half months after the patent issued. *Id.*, 26 USPQ2d (BNA) at 1095. During the period after issuance of the patent, 1,939 prostheses were shipped without marking. *Id.*, 26 USPQ2d (BNA) at 1095. Relying on *Hazeltine Corp. v. Radio Corp. of Am.*, 20 F. Supp. 668, 35 USPQ 438 (S.D.N.Y. 1937), the district court concluded that, under section 287(a), AMS was "obliged to have marked all Hydroflexes subsequent to issue [sic] of the patent, except that it is allowed a relatively small number to be shipped unmarked as it readies the marking process." 794 F. Supp. at 1391, 26 USPQ2d (BNA) at 1095 (citing 5 Donald S. Chisum, *Patents*, §§ 20.03[7][c][iii] n.109 and [c][iv] & n.133). The district court found that AMS failed to comply with section 287(a) because it had shipped more than a de minimis number of products after the patent issued without the requisite marking. *Id.* at 1392, 26 USPQ2d (BNA) at 1095.

AMS argues that the district court erroneously interpreted section 287(a). Under the correct interpretation of section 287(a), AMS asserts that it is entitled to damages from the time that it began consistently marking its product, thereby satisfying the statutory requirement. According to AMS, the district court's reliance on *Hazeltine* is misplaced, because that case was decided under

Revised Statute 4900, ch. 67, 44 Stat. 1058-59 (1927), the predecessor statute to the current section 287(a). R.S. 4900 provided that "it shall be the *duty* of all patentees . . . to give sufficient notice to the public that the same is patented . . ." (emphasis added). In 1952, Congress amended R.S. 4900 to become the present section 287(a), changing the language to make marking permissive rather than mandatory, so that a "patentee . . . *may* give notice to the public" by the specified marking. Act of July 19, 1952, ch. 950, § 287, 66 Stat. 813. Although the legislative history does not shed much light on Congress's intent regarding this specific language change, it is clear that the amendments were meant to reorganize and clarify the prior provisions.[14] AMS argues that since *Hazeltine* and the 1952 amendments, the courts have interpreted the new marking provision to allow damages from the point at which the statute is complied with by

---

[14] The legislative history of section 287(a) is rather sparse, but the purpose of the amendments was generally described in the Senate Report as follows:

> The next few sections relate to . . . [*inter alia*] marking and notice; all of which together replace present statutes on suits, with a good deal of reorganization in language to clarify the statement of the statutes.
>
> * * * *
>
> Section 287 - Section Revised
>
> Based on title 35, U.S.C., 1946 ed., § 49 (R.S. 4900, amended Feb. 7, 1927, ch. 67, 44 Stat. 1058).
>
> Language is changed. The proviso in the corresponding section of existing statute is omitted as being temporary in character and now obsolete.

S. Rep. No. 1979, 82d Cong., 2d Sess. 9, 30 (1952), *reprinted in* 1952 U.S.C.C.A.N. 2394, 2403, 2423.

fully marking the patented device. AMS also argues that Hazeltine is not applicable to the present situation, because in that case, marking was haphazard and, therefore, the statute was never fully complied with at any time.

Specifically, AMS points to *Slimfold Manufacturing Co. v. Kinkead Industries, Inc.*, C.A. No. 1:78-CV-1978-JOF, 1990 WL 512961 (N.D. Ga. May 29, 1990), *aff'd*, 932 F.2d 1453, 18 USPQ2d (BNA) 1842 (Fed. Cir. 1991). In *Slimfold*, the patentee commercialized the invention before the patent issued on May 14, 1974, but did not begin marking the patented product until November 1, 1977. *Id.*, slip op. at 16. The defendant began infringing in June 1977, the first actual notice of infringement was given in March 1978, and suit was filed in October 1978. *Id.* at 10, 16, 1. The district court held that Slimfold was entitled to damages from November 1, 1977, when it began to consistently mark its patented products. In reaching this conclusion, the court reasoned that:

> The statute does not require marking within a particular time after issuance of a patent. Both the Fifth and Sixth Circuit Courts of Appeal have so held. *Wm. Bros. Boiler & Mfg. Co. v. Gibson-Stewart Co.*, 312 F.2d 385, 386, 136 USPQ (BNA) 239, 240 (6th Cir. 1963); and *Bros, Inc. v. W.E. Grace Mfg. Co.*, 320 F.2d 594, 599, 138 USPQ (BNA) 357, 359 (5th Cir. 1963): "The Court points out that there is '. . . nothing in the statute requiring marking or notice within any period after issue as a condition for recovery of damages for infringement. . . .' " Liability for infringement begins with marking (or actual notice) whenever that occurs.

Id. at 32-33. On appeal, the Federal Circuit specifically affirmed the district court's award of damages as of the marking date, although the specific question of the proper interpretation of section 287(a) was not before the court. 932 F.2d at 1456, 1459, 18 USPQ2d (BNA) at 1845, 1847.

As noted by the district court in *Slimfold*, both the Fifth and Sixth Circuits have in the past specifically interpreted section 287(a) to allow damages from the time that actual marking begins or from the time of actual notice of infringement, whichever comes first. In *Wm. Bros Boiler & Manufacturing Co. v. Gibson-Stewart Co.*, 312 F.2d 385, 136 USPQ (BNA) 239 (6th Cir. 1963), the Sixth Circuit held that although the patentee failed to mark its patented devices for nine months after the date that the patent issued, he was entitled to recovery of damages from the time of compliance with the marking provisions of the statute. *Id.*, 136 USPQ (BNA) 239. The holding was based on the district court's reasoning that

> "Unless and until the patentee marks his patent or serves actual notice upon an alleged infringer he can recover no damages, but . . . nothing in the statute requires marking or notice within any period after issue as a condition for recovery of damages for infringement. . . . The penalty for failure to do either [is] limited to denial of damages for infringement at any time prior to compliance with the requirements of the statute."

Id. at 386, 136 USPQ (BNA) at 240. In a related case, *Bros, Inc. v. W.E. Grace Manufacturing Co.*, 320 F.2d 594, 138 USPQ (BNA) 357 (5th Cir. 1963), the Fifth

Circuit followed the same reasoning in reversing the district court's limitation of damages to the filing date of the lawsuit, allowing recovery of damages from the date of marking.

Similarly, in *Briggs v. M&J Diesel Locomotive Filter Corp.*, 228 F. Supp. 26, 63-64, 141 USPQ (BNA) 96, 127 (N.D. Ill. 1964), *aff'd*, 342 F.2d 573, 144 USPQ (BNA) 701 (7th Cir. 1965), the district court held that despite a two year delay in marking, the patentee was entitled to recover damages for infringement undertaken after marking began. Likewise, in *Mosinee Paper Corp. v. James River Corp.*, 1992 U.S. Dist. LEXIS 2425, 22 USPQ2d (BNA) 1657, 1662, 1992 WL 41690 (E.D. Wis. 1992), the district court determined that patentee was entitled to full recovery of damages where patentee began to mark the product in 1980, prior to infringement, even though the patent in suit issued on August 21, 1979.

MEC fails to adequately distinguish these cases or to convince us that their rationale is unsound. MEC cites a number of authorities in support of the district court's interpretation of the statute that marking of all patented products must begin immediately after issuance of the patent, subject to the *de minimis* exception of *Hazeltine*.[15]

---

[15] MEC cites numerous cases standing for the proposition that *all* patented articles must be marked after issuance of the patent. *The Providence Rubber Co. v. Goodyear*, 76 U.S. (9 Wall.) 788, 801, 19 L. Ed. 566 (1869) (decided under the marking statute of 1861, Act of March 2, 1861, ch. LXXXVIII § 13, 12 Stat. 249 (1863)); *Crier v. Innes*, 170 F. 324, 326 (2d Cir. 1909) (decided under R.S. 4900, U.S. Comp. Stat. 1901, p. 3388); *Gordon v. Easy Washing Mach. Corp.*, 39 F. Supp. 202,

(continued...)

These cases were all decided under the predecessor statutes to section 287(a) and, therefore, are not controlling on the interpretation of the present statute. As discussed above, since the statute was amended in 1952, the cases which specifically address this issue have interpreted section 287(a) to allow damages from the time when marking begins in compliance with the statute or actual notice is given, whichever comes first.[16]

---

[15] (...continued)
203, 49 USPQ (BNA) 321, 322 (N.D.N.Y. 1941) (decided under R.S. 4900, ch. 67, 44 Stat. 1058-59 (1927)); *Kilgore Mfg. Co. v. Triumph Explosives, Inc.*, 37 F. Supp. 766, 775, 49 USPQ 51, 53 (D. Md. 1941) (decided under R.S. 4900); *Matthews & Willard Mfg. v. National Brass & Iron Works*, 71 F. 518 (E.D. Pa. 1895) (decided under the marking statute of 1870, Act of July 8, 1870, ch. CCXXX § 38, 16 Stat. 203 (1871)). All of these statutes under which MEC's authorities were decided imposed a *duty* to mark on the patentee.

[16] Although other cases appear to be contradictory, they do not address the specific factual situation presented here. For example, *General Electric Co. v. Sciaky Bros., Inc.*, 304 F.2d 724, 726, 134 USPQ (BNA) 55, 57 (6th Cir. 1962), has been cited for the proposition that *all* patented products must be marked. All that *General Electric* says, however, is that "in view of General Electric's failure to mark its products as required by statute, or to give any notice of infringement, it could not, in any event, recover damages for infringements occurring prior to the filing of the action for infringement." (citations omitted). This case clearly does not address the situation where marking was fully complied with at some date after issuance. *See also Maxwell v. Baker*, 805 F. Supp. 728, 26 USPQ2d 1241 (D. Minn. 1992) (fact issue existed as to licensees failure to mark patented products); *In re Yarn Processing Patent Validity Litig.*, 602 F. Supp. 159, 168, 225 USPQ (BNA)
(continued...)

Although not binding on this court, we find the reasoning of the post-1952 cases highly persuasive. The plain language of section 287(a) does not provide any time limit by which marking must begin, nor does the legislative history indicate any such limitation.[17] Congress structured the statute so as to tie failure to mark with disability to collect damages, not failure to mark *at the time of issuance* with disability to collect damages. Furthermore, allowing recovery of damages from the point of full compliance with the marking statute furthers the policy of encouraging marking to provide notice to the public, even if initial marking after issuance of the patent is delayed. The sooner one complies with the marking requirements, the more likely one is to maximize the period of time for recoverable damages. To prevent recovery of damages for failure to immediately mark, however, provides no incentive for a patentee who inadvertently or unavoidably fails to mark initially to mark in the future.

Moreover, preventing recovery of damages for an initial failure to mark does not remedy the problem of having unmarked products in the marketplace. Any

---

[16] (...continued)
765, 771 (W.D.N.C. 1984) (licensees of patent failed to mark products); *Miller v. Daybrook-Ottawa Corp.*, 291 F. Supp. 896, 158 USPQ (BNA) 635 (N.D.Ohio 1968) (inconsistent marking by patentee).

[17] The legislative history cited by MEC referring to the requirement to mark *all* or *each* patented article is not responsive to the question of whether Congress intended to deny damages even after the patentee begins to mark all patented articles.

products entering the market prior to issuance of the patent will not be marked. Even the *Hazeltine* court recognized that "it is not the number of articles seen by the defendant which is controlling on an issue of marking . . . but whether the patentee performed this statutory duty which was a prerequisite to his *in rem* notice to the world." *Hazeltine*, 20 F. Supp. at 671, 35 USPQ (BNA) at 442. Therefore, once marking has begun in compliance with the statute, *in rem* notice is provided and there is no reason to further limit damages on this account.

In light of the permissive wording of the present statute, and the policy of encouraging notice by marking, we construe section 287(a) to preclude recovery of damages only for infringement for any time prior to compliance with the marking or actual notice requirements of the statute. Therefore, a delay between issuance of the patent and compliance with the marking provisions of section 287(a) will not prevent recovery of damages after the date that marking has begun. We caution, however, that once marking has begun, it must be substantially consistent and continuous in order for the party to avail itself of the constructive notice provisions of the statute.

Applying this statutory construction to the facts of this case, AMS is entitled to damages from the time when it either began marking its products in compliance with section 287(a) or when it actually notified MEC of its infringement, whichever was earlier. AMS began marking its products about two months after issuance of the '765 patent and it began externally shipping those marked products on October 15, 1986. The district court found that actual notice of infringement was not given

until the lawsuit was filed on October 28, 1987. AMS has not shown that the district court's finding as to actual notice was clearly erroneous.[18]

We hold that AMS is entitled to damages from the time that it began shipping its marked products, October 15, 1986, rather than the filing date of the lawsuit as found by the district court, because AMS was in compliance with the marking statute at that time. The date that AMS began marking its products is irrelevant for purposes of the statute, because marking alone without distribution provides no notice to the public where unmarked products are continuing to be shipped. The purpose of the constructive notice provision is "to give patentees the proper incentive to mark their products and thus place the world on notice of the existence of the patent." *Laitram Corp. v. Hewlett-Packard Co.*, 806 F. Supp. 1294, 1296, 25 USPQ2d (BNA) 1827, 1834-35 (E.D. La. 1992). The world cannot be "put on notice" if the patentee marks certain products, but continues to ship unmarked products. Therefore, AMS was not in full compliance with the marking statute while it continued to ship its unmarked products, which continued to mislead

---

[18] AMS argues that MEC was notified in August 1986 by its own counsel, Krieger, that MEC was infringing the '765 patent. This is clearly not what was intended by the marking statute. Section 287(a) requires a party asserting infringement to either provide constructive notice (through marking) or actual notice in order to avail itself of damages. The notice of infringement must therefore come from the patentee, not the infringer. *Devices for Medicine, Inc. v. Boehl*, 822 F.2d 1062, 1066, 3 USPQ2d (BNA) 1288, 1292 (Fed. Cir. 1987) ("Absent notice, [infringer's] 'knowledge of the patents' is irrelevant.").

the public into thinking that the product was freely available. Full compliance was not achieved until AMS consistently marked substantially all of its patented products, and it was no longer distributing unmarked products. We therefore remand this portion of the case to the district court for a proper determination of damages consistent with this decision.

B. Patent Marking Relating to Method Claims

AMS argues that the district court erred in limiting its recoverable damages from the infringed method claims of the '765 patent pursuant to section 287(a). The law is clear that the notice provisions of section 287 do not apply where the patent is directed to a process or method. *Bandag, Inc. v. Gerrard Tire Co., Inc.*, 704 F.2d 1578, 1581, 217 USPQ 977, 979 (Fed. Cir. 1983) (citing *Wine Ry. Appliance Co. v. Enterprise Ry. Equip. Co.*, 297 U.S. 387, 80 L. Ed. 736, 56 S. Ct. 528 (1936)); *Hanson v. Alpine Valley Ski Area, Inc.*, 718 F.2d 1075, 1083, 219 USPQ (BNA) 679, 685 (Fed. Cir. 1983) (noting that section 287(a) does not apply where only method claims are infringed). The district court, however, relied on *Devices for Medicine, Inc. v. Boehl*, 822 F.2d 1062, 3 USPQ2d (BNA) 1288 (Fed. Cir. 1987), in holding that "where there are both product and method claims being claimed infringed, the patentee must mark the product." 794 F. Supp. at 1391, 26 USPQ2d (BNA) at 1095.

In *Devices for Medicine*, the court noted that in *Bandag* and *Hanson*, a distinction was made between cases "in which only method claims are asserted to have been infringed" and cases where a patentee alleges in-

fringement of both the apparatus and method claims of the same patent. *Devices for Medicine*, 822 F.2d at 1066, 3 USPQ2d (BNA) at 1292. The *Devices for Medicine* court further stated that because the method claims of the patent were directed to the use of the claimed product, "having sold the product unmarked, [the patentee] could hardly maintain entitlement to damages for its use by a purchaser uninformed that such use would violate [patentee's] method patent." *Id.*, 3 USPQ2d (BNA) at 1292.

AMS contends that *Devices for Medicine* is inapposite, because in that case the patent contained product claims and claims covering the use of the same product. AMS asserts that the sale of a product carries an implied license to use it as a matter of law; therefore failing to mark a patented product rationally creates an expectation of receiving a right from the seller to use it for its customary purposes. By contrast, AMS argues that the '765 patent involves methods of making and sterilizing the patented product and that sale of a product does not grant any implied license to make an additional product or to use a particular manufacturing process to make it. Therefore, AMS asserts that the rationale of *Devices for Medicine* should not apply and that section 287(a) has no application to the instant method claims.

We find AMS's distinction of the claims in *Devices for Medicine* from those in the present action to be meaningless within the context of section 287(a). The purpose behind the marking statute is to encourage the patentee to give notice to the public of the patent. The reason that the marking statute does not apply to method claims is that, ordinarily, where the patent claims are directed to

only a method or process there is nothing to mark. Where the patent contains both apparatus and method claims, however, to the extent that there is a tangible item to mark by which notice of the asserted method claims can be given, a party is obliged to do so if it intends to avail itself of the constructive notice provisions of section 287(a).

In this case, both apparatus and method claims of the '765 patent were asserted and there was a physical device produced by the claimed method that was capable of being marked. Therefore, we conclude that AMS was required to mark its product pursuant to section 287(a) in order to recover damages under its method claims prior to actual or constructive notice being given to MEC.

C. Attorney Fees

We deny AMS's request for attorney fees based on its allegation that MEC's jury trial argument was so frivolous and unreasonable as to warrant sanctions. Although we found MEC's arguments on this issue to be meritless, this was but one issue in an appeal which otherwise was not frivolous. Moreover, meritlessness does not prove frivolity. "Even though an appeal is judged 'entirely without merit,' . . . it may have presented an arguable basis for reversal, and thus not qualify for sanctions." *Biodex Corp. v. Loredan Biomedical Inc.*, 946 F.2d 850, 863-64, 20 USPQ2d (BNA) 1252, 1263 (Fed. Cir. 1991) (citation omitted), *cert. denied*, 119 L. Ed. 2d 579, 112 S. Ct. 2957 (1992). Therefore we deny AMS's request for sanctions.

CONCLUSION

AFFIRMED-IN-PART, REVERSED-IN-PART and REMANDED.

87-C-1236 (JPS)

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

AMERICAN MEDICAL SYSTEMS, INC.,

Plaintiff,

v.

MEDICAL ENGINEERING CORPORATION,

Defendant.

June 25, 1992

OPINION

STADTMUELLER, District Judge.

I. Introduction

This action was filed by American Medical Systems, Inc. (AMS) against Medical Engineering Corporation (MEC) in October 1987. AMS owns, via assignment from William Klatt, U.S. Patent Number 4,597,765, entitled "Method and Apparatus for Packaging a Fluid Containing Prosthesis." AMS claims MEC has infringed the patent. MEC has counterclaimed for a declaration of invalidity of the patent, and for relief due to AMS' alleged breach of certain agreements between the parties. The case was tried to the court, sitting without a jury, for three weeks. Pursuant to Fed. R. Civ. P. 52 the following constitutes the court's findings of fact and conclusions of law.

II. The Parties and Jurisdiction

AMS is a Minnesota corporation with its principal place of business in Minnetonka, Minnesota. Its business is devoted to the research, development, manufacture and sale of penile prostheses and other medical products of a urological nature. AMS was an independent company until May 1985, when it became a wholly-owned subsidiary of Pfizer Inc.

MEC is a Delaware corporation with its principal place of business in Racine, Wisconsin. MEC's business, too, is devoted to medical products, including mammary and penile prostheses and urinary stents. Since 1982 MEC has been a wholly-owned subsidiary of the Bristol Myers-Squibb Corporation.

The jurisdiction of the court arises under 28 USC 1338(a). Venue is proper in this district pursuant to 28 USC 1400(b).

III. The Evolution of the Penile Prosthesis

Erectile dysfunction affects more than five million men in the United States. The causes range from the physiological to the psychological. Common physical causes include diabetes, neurological or vascular disease, prostrate surgery and spinal cord injuries, to name but a few. One of the recognized treatments for erectile dysfunction is the insertion of a penile protheses.

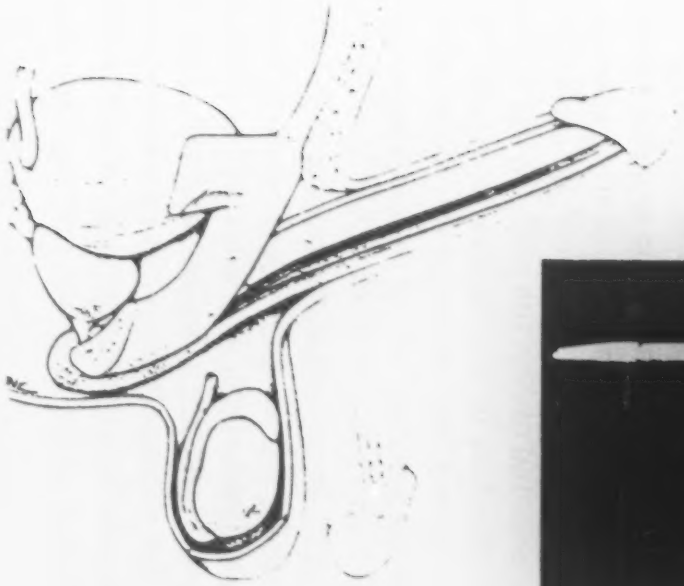
The first modern penile prosthesis, known as "rods" and "multi-component inflatables," were developed in the early 1970s and continue to be actively marketed. Both AMS and MEC manufacture the rod prosthesis: respec-

tively, the AMS 600 (Figure A)[1] and the MEC Flexi-Rod. The "rod" type device is generally comprised of cylinders of silicone material, sometimes with a metal wire core. Two cylinders are surgically implanted in the corpora cavernosa of the penis. The cylinders are always rigid, and at coitus are simply physically manipulated into position. The advantages of this device are that it is simple, inexpensive, easy to implant and essentially free from mechanical failure. On the other hand, the rods permanently rigidized the phallus, resulting in a lack of flaccidity and concomitant problems with concealment.

The multi-component inflatable device such as the AMS 700CX (Figure B) consists of a reservoir, at least one pump, and a pair of inflatable cylinders, all connected by tubing. Hence, the product is often referenced as a "three-piece" device. The reservoir is implanted in the patient's abdominal cavity, the pump in the scrotum, and the pair of cylinders in the corpora cavernosa. In operation, fluid is forced from the reservoir to the cylinders by pumping at the scrotum, which pressurizes and rigidizes the cylinders and phallus. Thereafter, a release valve in the pump can be activated to return the fluid to the reservoir, deflating the cylinders and returning the phallus to a flacid state. The advantages of this device are its superior rigidity, excellent flaccidity and concealment, and the natural look and feel it afforded. However, it requires more invasive surgery, is more expensive, and is more prone to malfunction.

---

[1] Figures A, B and E appear in Exhibit 22.



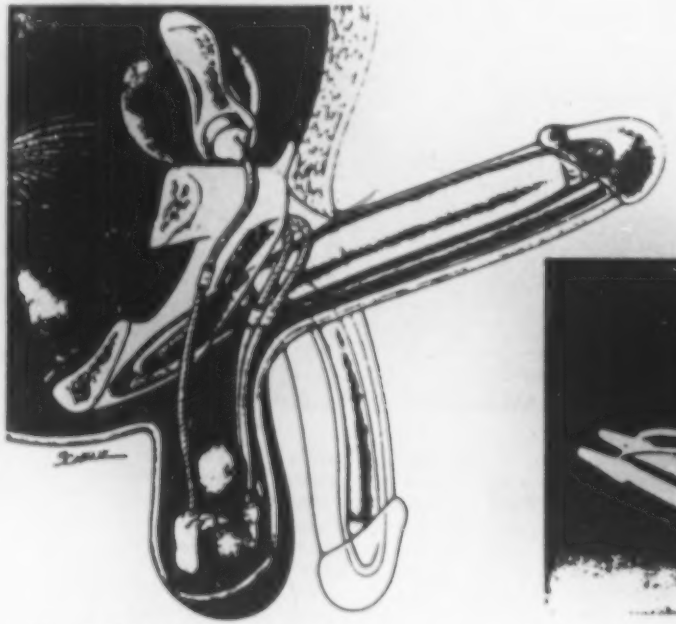
AMS Malleable 600™
Penile Prosthesis

The AMS Malleable 600™ Penile Prosthesis is permanently firm, but can be bent to an erect position for intercourse and close to the body for concealment.

Stainless-steel core

Malleable rod

Figure A



AMS 700CX™ Inflatable Penile Prosthesis

The AMS 700CX™ Inflatable Penile Prosthesis mimics the process of a normal erection. Squeezing the pump bulb in the scrotum a number of times makes the penis firm and erect. Compressing the release valve on the side of the pump returns the penis to a relaxed position.

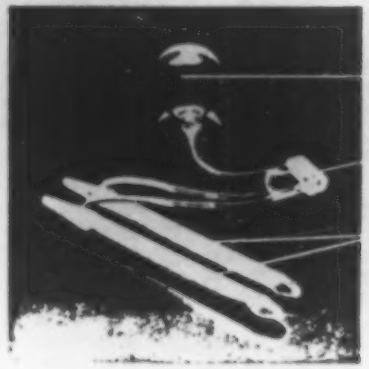


Figure B

Later in the 1970s both AMS and MEC independently began working on a "self-contained" prosthesis. Both designs consisted of a hydraulic, inflatable, fluid-permeable silicone cylinder with the reservoir and pump contained in the cylinder. Both efforts were geared to obtaining the benefits of the three-piece device while avoiding the multiple components and invasive surgery of the three-piece on the one hand and the permanent rigidity of the rods on the other.

MEC reached the market first, in October 1984, with a product called "Flexi-Flate." (Figure C).[2] The prosthesis was shipped sterile but unfilled—that is, without the saline necessary to drive the hydraulic components of the device. This "dry pack" configuration created problems.

---

[2] Figure C appears in Exhibit 35 at page 3.

BEST AVAILA

BLE COPY

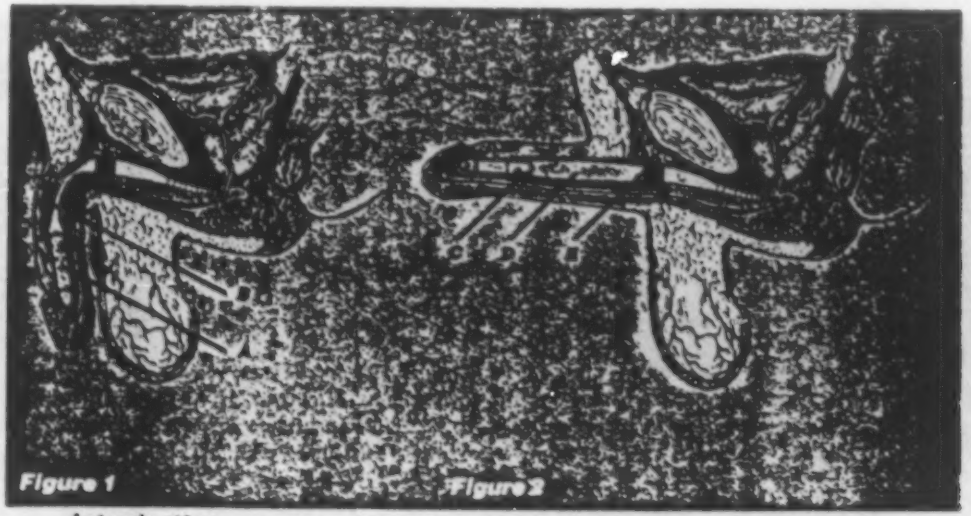


Figure 1 Figure 2

Introduction

The Flexi-Flate is a totally self-contained inflatable penile implant similar in appearance to rod-type prostheses such as the Flexi-Rod® II. Unlike multi-component inflatable devices the Flexi-Flate consists of two cylinders and is totally implanted within the corpora. This implant is a result of a long-term commitment by Medical Engineering Corporation to develop a simpler inflatable penile prosthesis.

The Flexi-Flate allows the patient with erectile impotence to create an erection by simply squeezing the pump ***(A-Figure 1)*** located proximally to the glans penis.

The erection is created when fluid is pumped from an expandable outer cylinder ***(B-Figure 1)*** through special one-way check valves ***(C-Figure 2)*** into a non-expandable inner cylinder ***(D-Figure 2)*** The penis becomes erect and rigid as fluid is transferred to the inner cylinder. To deflate the implant and return the penis to the flaccid state, the patient simply bends his penis at the base. This increases the pressure in the non-expandable inner cylinder. When the pressure in the inner cylinder exceeds the preset pressure relief valve setting, fluid is forced through the relief valve ***(E-Figure 2)*** and back into the outer cylinder.

Figure C

First, quality control was compromised, since MEC was unable to conduct final functional quality control testing on all the devices. The best that could be done was to test a sample and hope it was representative. There were also problems associated with filling the prosthesis in the operating room. The doctor had to open the patient to determine the appropriate size prosthesis. Then, while the patient was open, the doctor had to fill the two Flexi-Flate cylinders with saline and aspirate them in a procedure that could easily take up to 30 minutes for a surgeon new to the process. The saline had to be specially filtered during filling to avoid the small particulate matter normally found even in the sterile, hospital-grade variety; such particulate can clog the sensitive valves in the cylinders. (Ex. 36 at 7). In addition, the amount of saline to be added to a cylinder was less than a tablespoon, about 8-12 cc, depending on the size of the prosthesis. Precision was critical; underfilling would produce a prosthesis that did not properly rigidize, and overfilling would create a prosthesis which would not deflate properly. The record reflects a number of instances of improper filling during surgeries utilizing the dry-pack prosthesis. (Exs. 55, 58-61, 92-95).

IV. Klatt's Invention

In the 1970's AMS began developing its own self- contained penile prosthesis, called the Hydroflex. At least as early as January 1981 AMS knew that having a prefilled and sterile device would be important in the long run. (Ex. 533). By November 1983, AMS was actively seeking a method of providing a prefilled sterile device to the surgeon for surgical implant. (Tr. 1673-74; Ex. 511). The

responsibility for solving the problem was assigned to AMS engineer William Klatt.[3]

Klatt spoke with the designer of the Hydroflex device about its design characteristics. He also spoke to the marketing department to find out what kind of package characteristics they would want. He was told they wanted a small, easy to open, two layer package. This packaging would allow a non-sterile nurse to open the non-sterile outer package and present the sterile inner package to a sterile nurse to open in the operating field. Mr. Klatt also spoke with a number of packaging material suppliers, including Kapak Corporation, whose pouches were ultimately used to package the Hydroflex. (Tr. 1675, 1687-1690). In addition, he discussed sterilization methods and sterilization validation with an AMS quality control engineer, John Westrom, and an independent consultant, Skyland Laboratories. (Tr. 1674-76). Mr. Klatt had generally conceived his solution by December 1983: "Place [prefilled Hydroflex] in package, fill package with .9% salt solution, seal package, sterilize." (Tr. 1678; Ex. 511 at Bates 217). Testing and validation of the solution, however, continued until at least late 1984. (Tr. 1684; Ex. 511).

The wet pack configuration had clear advantages over the dry pack. The prosthesis could be accurately filled

---

[3] Mr. Klatt has a bachelor of science degree in electrical engineering. It appears Mr. Klatt was somewhat of a jack-of-all-trades engineer at AMS. His previous work for AMS included design of electronic circuitry used in diagnostic equipment; mechanical and pneumatic design of an unspecified nature; and the design of wood and metal cabinets. (Tr. 1665-67).

with particulate-free saline, and the device could be sterilized by the manufacturer before shipment. This guaranteed quality control to the fullest extent possible by eliminating the intervening operating room filling procedure before implantation. As a result, the functional properties of the device would not change from the time of manufacture to the time of implantation. In addition, since there was no filling to be done in the operating room, the surgeon was able to immediately implant the device. The elimination of the intervening step reduced the amount of time the patient was under anesthesia, as well as the overall cost of the surgical procedure.[4]

AMS sought to patent the combination of prefilled Hydroflex and packaging created by Mr. Klatt. The invention is fully described in the patent, and discloses how to make and use the invention to obtain its benefits. The patent claims are divided into product claims and method claims. The former, claims 1-12 and 21-24, define the prefilled and presterilized packaged prosthesis. Claim 2 is representative of the product claims:[5]

> A packaged fluid containing prosthesis adapted to be implanted in a sterile condition, said prosthesis comprising:
>
> > a prosthetic device, wherein said prosthetic device is an inflatable penile prosthesis, having a closed, permeable housing defining a fluid containing chamber;

---

[4] Dr. Bruskewitz estimated the cost of operating room time to be approximately $ 20.00 per minute.

[5] Written in independent form. Ex. 113.

> a sealed, substantially fluid impenetrable enclosure surrounding said housing and defining a liquid retaining space between said enclosure and said housing, said enclosure adapted for separation from said device prior to implantation of said device;
>
> and said enclosure containing a liquid in said space with activities that substantially match the activities of the fluid in said chamber such that the mass transfer gradient across the permeable housing is insubstantial.

The other product claims add various other limitations to this structure. The method claims, claims 14-15 and 18-20, define the method of making and sterilizing a packaged fluid-containing prosthesis. Claims 18 is representative of the method claims:[6]

> A method of packaging a fluid containing prosthesis adapted to be implanted in a sterile condition, said method comprising the steps of:
>
> filling a closable permeable housing within a prosthetic device with a fluid;
>
> enclosing said prosthetic device within an enclosure which contains a liquid with activities that substantially match the activities of the fluid within the housing, thereby rendering insubstantial the mass transfer gradient across the permeable housing;

---

[6] Written in independent form. Ex. 114.

> sealing said enclosure about said prosthetic device to define a sealed substantially fluid impenetrable barrier to fluid migration;
>
> enclosing said enclosure within an outer bag; and
>
> sterilizing said prosthetic device in a liquid filled state within said enclosure and said outer bag.

Initially, the PTO examiners found the Klatt invention to be obvious in view of the prior art:

> The Applicant's invention differs from Riall in view of Campbell only in the particular device he has chosen to store in the container. In as much as the basic problems of keeping the device wet while avoiding problems of osmosis are addressed and solved in Riall in view of Campbell, the Examiner views the mere substitution of one prosthesis within the package (such as a penile implant) over another as obvious to one of ordinary skill in the art.

Ex. 2 at 34. After the rejection, however, the examiners met with Mr. Klatt, his patent attorney, and an AMS official. *Id.* at 37. The examiners then reversed their earlier finding and held that the Klatt claims distinguished over prior art.

The argument that convinced the examiners is summarized in Response A to Paper No. 4:

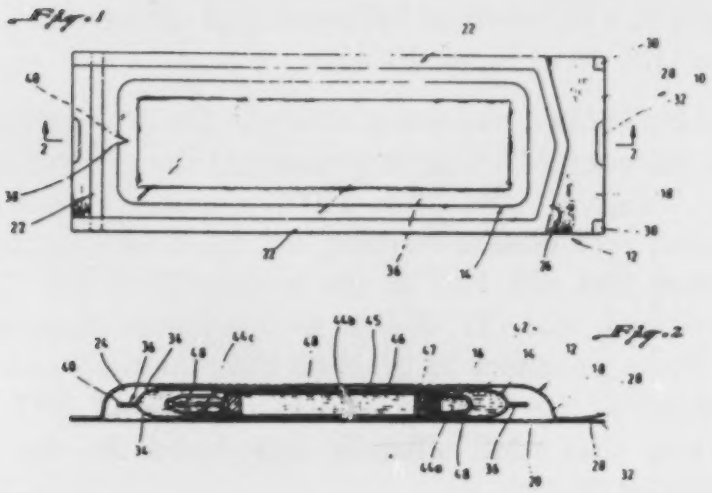
> The prior art fails to teach a packaged fluid containing prosthesis with *inter alia* a prosthetic device that includes (1) a closed permeable housing

defining a fluid containing chamber together with (2) an enclosure containing a liquid with activities that substantially match the activities of the fluid within the chamber such that the mass transfer gradient across the permeable housing is insubstantial, as set forth in pending independent claim 1. In such an arrangement it is possible to precisely engineer or control the volume of fluid in that chamber despite the ability, under atmospheric or other conditions, for the fluid to move through the walls of the housing. This is clearly a problem which was neither recognized or solved by any of the prior art of record.

Ex. 2 at 39.

The Klatt patent issued on July 1, 1986. (Figure D).[7]

Figure D

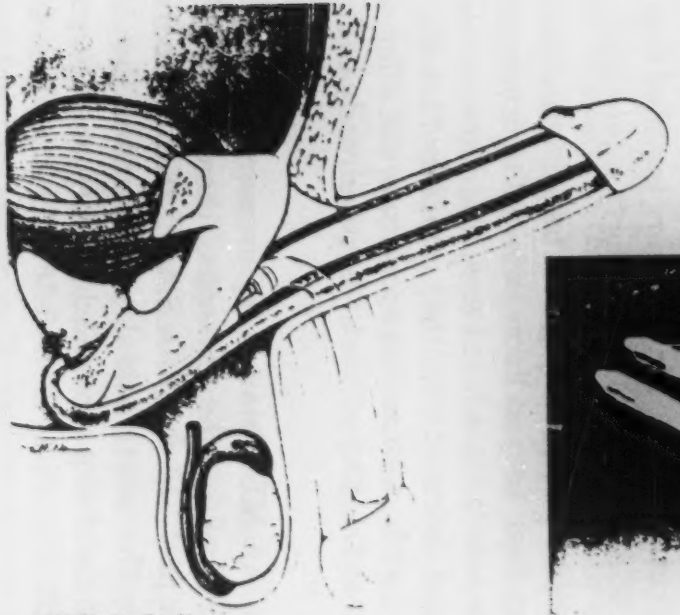


[7] Figure D appears in Exhibit 1.

V. MEC's Activities

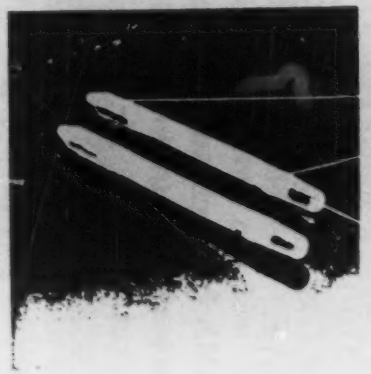
At least as early as April 1984, MEC intended to market a prefilled and sterile Flexi-Flate and (Tr. 1156-57) in early October 1984, MEC assigned the project to senior project engineer Jay Goldberg. (Tr. 1156-57, Ex. 962). Mr. Goldberg's personal project notebook indicates that the earliest packaging configurations for the prefilled and sterile Flexi-Flate utilized a rigid, vapor impermeable tube. The earliest configuration was to place the prefilled prosthesis into a tube surrounded by saline of the same osmolarity as that in the device. The tube was then capped. The inner tube was then enclosed in a slightly larger tube or pouch. (Ex. 116 at Bates 101400). In March 1985, Garry Carter, MEC's vice president of scientific affairs asked Mr. Goldberg to fill out an invention record for this configuration. (Ex. 116; Tr. 272, 277). Nevertheless, as of May 1985, an MEC product definition for the prefilled Flexi-Flate reversed the relationship of the pouch and tube; the prosthesis was to be placed in a saline-filled foil pouch and enclosed in a rigid tube. (Ex. 48 at Bates 105482).

Also in May, like many others in the urological products industry, Mr. Goldberg attended the annual American Urological Association (AUA) meeting. This is a significant professional meeting, attended by between one quarter and one half of the urologists in the United States each year. (Tr. 488) As a consequence manufacturers make an effort to promote their newest urological products at the meeting. It was at the May 1985 AUA meeting that AMS officially introduced the wet pack Hydroflex (Figure E).



AMS Hydroflex™ Self-Contained Penile Prosthesis

Squeezing the inflation pumps in the head of the penis a number of times inflates the AMS Hydroflex™ Self-Contained Penile Prosthesis. Compressing the deflation valves behind the head of the penis deflates the prosthesis to a concealable position.



rear reservoir

deflation valve

inflation pump

Figure E

This new product, the first prefilled and sterile self-contained prosthesis to reach the market, was received with great interest. The AMS booth received substantial traffic, both from urologists and (not surprisingly) from the competition. (Tr. 312, 488-89). Mr. Goldberg visited the booth. While he was there, he learned that AMS' packaging concept utilized a saline filled inner pouch containing the prosthesis, surrounded by a larger outer pouch. (Tr. 310-12). He reported his findings to MEC's R & D and marketing departments upon returning to the office. (Tr. 313).

Since AMS had beaten MEC to the punch on prefilling, there was pressure to get the prefilled Flexi-Flate into the market. (Tr. 312). Mr. Goldberg testified that following the AUA meeting, MEC's efforts intensified:

> We identified this prefilling as a feature that was necessary that we, you know, wanted to come out with. We saw it introduced and, you know, we—we decided there was another company that has come out with, we need to accelerate our efforts to speed up the project that we had already been working on.

(Tr. 402-03). An MEC marketing memo from May 31, 1985 similarly reflects the urgency of the situation: "We must have a prefilled device A.S.A.P." (Ex. 50 at Bates 106029). For the next several months after the AUA meeting, Mr. Goldberg continued to work on tube packaging concept. (Ex. 963; Tr. 315-16). Tests were run on the various configurations. The results did not prove promising: pouches blew open under the pressure of the autoclave; pouches in tubes developed holes during autoclaving; the tubes leaked due to the inability to get a

good ultrasonic weld between tube and cap. (e.g., Ex. 963 at Bates 101416, 101423; Tr. 322).

On July 11, 1985 Mr. Goldberg had the good fortune to stumble across Kapak Corporation while searching for autoclavable foil pouches. During his conversation with Kapak's sales representative, she remarked that the application he had in mind sounded familiar, because a company called AMS was using Kapak's foil pouches. (Ex. 963 at Bates 101419; Tr. 317). Kapak's representative sent autoclavable foil samples to Mr. Goldberg. On July 16, Mr. Goldberg received samples of Hydroflex from the marketing department, and he inspected the packaging. (Ex. 963 at Bates 101419; Tr. 318).

Mr. Goldberg began to test the double pouch system more intensively. (Ex. 963 at Bates 101419-23). The tube concept continued to experience problems; indeed, throughout this period, and despite repeated attempts, MEC was unable to produce a single successful rigid tube prefilled Flexi-Flate. (Tr. 1253-54). On August 23, Bob Boeck, MEC product manager, decided to go with the double pouch configuration. (Ex. 963 at Bates 101423; Tr. 322-23).

The documents of record reflect that the pressure on MEC to get a prefilled product into the market place continued to mount. From an August 11, 1985 capital appropriations request: "Physicians are now starting to turn toward the use of prefilled sterile penile prostheses rather than the conventional physician-filled implant" (Ex. 63 at 2); from a September 23, 1985 capital appropriations request: "[The purchase of equipment to produce prefilled Flexi-Flate] will put MEC on a more even footing with competitors and will result in a signifi-

cant increase in projected sales" (Ex. 62); from a February 19, 1986 marketing memo authored by product manager Bob Boeck:

> In the last several months, I've attended at least three key seminars and met with 40-50 urologists (San Francisco, Portland, Los Angeles, Boston, New York, San Antonio). Based on conversations with these doctors, the following is what I see shaping up in the marketplace:
>
> 1. Increasing objection to Flexi-Flate not being prefilled. Virtually every doctor who has commented on this aspect of the Flexi-Flate has indicated it adds unnecessarily to O.R. time, which increases cost to the patient. The doctors also see our not having prefilled as an inconvenience on their part and a step which they don't have to do through if they use the Hydroflex.

(Ex. 53).

The final product definition for the prefilled Flexi-Flate, dated May 5, 1986 states that the Flexi-Flate will be shipped in a double foil pouch configuration like Hydroflex:

> An implant is filled with saline and placed into the inner pouch, with the tail at the notched end. Fifty (50) ml of saline is added to the pouch and the pouch is sealed. The inner pouch is placed into the outer pouch with the tear notches at opposite ends. .5ml of saline is added to the outer pouch and the pouch is sealed.

(Ex. 56 at Bates 105455).

VI. MEC Attempts to Patent Wet Pack Flexi-Flate

MEC sought to patent its prefilled and presterilized self-contained device. Mr. Goldberg was asked by Garry Carter, MEC's vice president for scientific affairs, to submit an invention record for the purpose of filing a patent application for a prefilled Flexi-Flate. (Ex. 116; Tr. 268-70, 272). At the time he signed his invention record, no one questioned that the idea for a prefilled Flexi-Flate was Mr. Goldberg's. (Tr. 272). The invention record described the many advantages a prefilled Flexi-Flate would have over the unfilled Flexi-Flate being sold at the time. (Ex. 116 at Bates 101401; Tr. 273, 277-82).

On February 7, 1986, with full knowledge of AMS' Hydroflex and its configuration, MEC filed a patent application for a prefilled Flexi-Flate in the name of Jay Goldberg. (Ex. 117; Tr. 415-16). The Goldberg application was assigned to MEC. (Tr. 392). The application describes the significant advantages of the prefilled device over an unfilled device. (Tr. 342-44).

When Mr. Goldberg signed the application, he believed that he was the original and sole inventor and he was not aware of any material prior art. (Ex. 117; Tr. 339-42). Mr. Goldberg further believed at the time he filed his patent application that the combination of a double pouch and a prefilled self-contained inflatable penile prosthesis, with fluid in the pouch to keep fluid from coming out of the device, was new. (Tr. 396-97). When MEC's attorney prepared the application, it was reviewed by at least Mr. Goldberg, and MEC's attorney expected Mr. Goldberg to sign and the PTO to examine the application with the claims as filed. (Tr. 1373, 1376-80).

MEC and its attorneys fully participated in the selection of the prior art to be disclosed to the PTO. (Tr. 355-56). MEC's attorney was experienced and familiar with the prior art. (Tr. 1368-69, 1380-82).

MEC has suggested that the Goldberg patent application was limited to the use of a rigid tube or "non-expandable" outer enclosure, but this argument is unconvincing. The Goldberg application plainly teaches that a flexible double pouch can be used. (Tr. 348-53, 387-91). Both Mr. Goldberg and Mr. Carter, who was also involved in the Goldberg application, each admitted that claim 3 of the Goldberg application would cover AMS' Hydroflex. (Tr. 352-53, 414).

The PTO issued a restriction on MEC's application, requiring the attorney of record, Mr. Kryshak, to elect which invention he wished to pursue. He elected to proceed with claims 1, 2, 11 and 12. In February 1987, the PTO issued its first office action, which rejected claims 1 and 2 "as being unpatentable over Klatt in view of Lloyd." Claims 11 and 12 were rejected "as being clearly anticipated by Klatt." (Ex. 117 at 49). Thereafter, the application was abandoned. (Tr. 1387-88).

VII. Validity of the Klatt Patent

A patent shall be presumed valid, and each claim shall be presumed valid independently of the other claims. 35 USC 282. The burden is on the party asserting invalidity to prove it with facts supported by clear and convincing evidence. *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 872 (Fed. Cir. 1985).

The presumption of validity is premised on the expertise possessed by the Patent and Trademark Office interpreting the references and having familiarity with the level of ordinary skill in the art. *Bausch & Lomb, Inc. v. BarnesHind/Hydrocurve, Inc.*, 796 F.2d 443, 447 (Fed. Cir. 1986), *cert. denied*, 484 U.S. 823, 108 S. Ct. 85, 98 L. Ed. 2d 47 (1987). The deference accorded to the PTO's expertise is heightened where the prior art before the court is the same as that before the PTO. *Id.*

MEC contests the presumptive validity of the patent on the grounds that the invention was obvious from the prior art. 35 USC 103. The ultimate conclusion of obviousness is one of law, but the conclusion is based on the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 86 S. Ct. 684, 693, 15 L. Ed. 2d 545 (1966): 1) the scope and content of the prior art; 2) the difference between the prior art and the claims at issue; 3) the level of ordinary skill in the pertinent art at the time the invention was made; and 4) the objective evidence of nonobviousness, such as commercial success, satisfaction of a long-felt need, failure of others, recognition by the industry, and copying.

As the court embarks upon its obviousness inquiry, it is instructive to keep a recent caution by the Federal Circuit in mind:

> The obviousness standard, while easy to expound, is sometimes difficult to apply. It requires the decisionmaker to return to the time the invention was made. The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time. . . . That which may be made clear and thus 'obvious'

> to a court, with the invention fully diagrammed and aided by experts in the field, may have been a breakthrough of substantial dimension when first unveiled.

Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1050-51 (Fed. Cir. 1988).

A. Scope and Content of the Prior Art

The scope of the prior art is that art which is reasonably pertinent to the particular problem with which the inventor was involved. *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 722 F. Supp. 595, 605 (N.D. Cal. 1989) *citing In re Deminski*, 796 F.2d 436 (Fed. Cir. 1986). The scope of the prior art would include methods and materials used in medical and food packaging.

MEC's expert on the question of obviousness, Dr. James Goff, stated that he found the following prior art to be the most relevant to whether the Klatt patent was invalid for obviousness (Tr. 1939-40): 1) the Banko patent (Ex. 854) combined with the Mazzocco patent (Ex. 889); 2) the Naficy patent (Ex. 751); 3) the "suture" patents, Riall (Ex. 3) and Rynkiewicz (Ex. 507); 4) the canning and pickling of food (Tr. 1939-40); 5) Dr. Austad's patent, publication (Ex. 899), and experiments with tissue expanders.

The Banko patent teaches a method and apparatus for implanting a fluid-filled replacement lens in the human eye. The lens is to be made of a deformable "suitable plastic material" such as for example used in soft contact lenses; it is not apparent whether this material

is permeable or not. The lens may be filled with a sterile solution, gelatin, or plain or Ringers saline solution. (Ex. 854 at col. 2). Banko does not teach that the implant is to prefilled and presterilized by the manufacturer. (Tr. 1933). The Mazzocco patent teaches, among other things, an improved method of packaging an intraocular lens such that the optical parameters of the lens could be viewed from outside the bottle. A screw top bottle made of glass, stainless steel, titanium, or polymeric material such as silicone rubber is used; it is filled with a "suitable fluid" such as saline, distilled water, or alcohol. The lens is suspended from a holder affixed to the cap. The result is designed to be autoclavable. (Ex. 889 at col. 4 lines 25-28, col. 6 lines 45-65, and col. 7 lines 29-35).

The Naficy patent is formally titled "Breast Prosthesis with a Biologically Absorbable Outer Container." As its name suggests, the patent teaches a breast prosthesis comprised of an inner core of biologically acceptable material surrounded by silicone rubber sac in the preferred embodiment. The inner core is in turn surrounded by an outer sac made of biologically absorbable material; there is saline between the inner and outer membranes. The whole unit is implanted, and with time the outer membrane is absorbed into the body.

For present purposes, there is no material differences between the two suture patents. (Tr. 1967-68). Mr. Klatt cited the Riall patent in his application. In Riall, the sutures are packaged in an inner envelope which is enclosed in two more envelopes, each envelope nested inside the other. The interior envelope may contain the sutures dry or in a conditioning liquid. Sutures which require a conditioning liquid are packed in ethyl alcohol, or

a mixture of ethyl alcohol, isopropyl alcohol, and water, or some other conventional conditioning liquid. In the Rynkiewitz patent, the suture is packed in a packet containing conditioning liquid such as methanol or ethanol. This packet is in turn packaged in another, larger packet.

Dr. Goff also claimed that he found the canning and pickling of food to be relevant. He testified that in canning, the food item—he used the example of green beans—is blanched in hot salt water. This process purges the gases from the bean, densifies it, and fills the bean with blanching fluid. The beans are then put in a can, the headspace is purged to remove excess air, and a lid is put on. The can is then placed in a pressure vessel and subjected to a steam cooking process. (Tr. 1864-65). Dr. Goff stated that the scientific principle involved in the blanching process was osmosis. *Id.*

Dr. Goff also testified that he found the patent and work of Dr. Austad to be relevant. Dr. Austad has a patented tissue expander which is of record in this case. (Ex. 503). The patent teaches a surgically implantable device for expanding skin and mucous tissue. The device involves the use of a partially collapsed sealed envelope formed from a material which is permeable to extracellular body fluid, such as silicone. The envelope contains a material which establishes an osmotic potential across the envelope wall, such as dry sodium chloride. Body fluid crosses the membrane to fill the envelope. As the envelope fills it expands the adjacent tissue. There is no disclosure in the patent or Dr. Austad's publication (Ex. 899) of preparing or shipping *prefilled* implants which are *then* implanted in the body.

Dr. Goff also found Dr. Austad's post-experiment storage of tissue expanders to be relevant. Basically, Dr. Austad testified that he would store the filled tissue expanders in jars of saline. For the most part, the salt concentration in the saline initially differed from that in the tissue expander. (Tr. 1585). However, Dr. Austad also testified that he performed one experiment where the tissue expander had much more than an isotonic amount of saline inside. To store these implants, saline plus additional sodium chloride crystals were poured into the jar; as a result, the salt concentration inside the implant and outside the implant was the same. (Tr. 1585-86).

Dr. Austad also testified that his experiments were "essentially" accessible to the public. (Tr. 1588). He said various people including students, surgeons, drug representatives and the like passed through his laboratory. But it became clear to the court on cross examination that while various persons may have entered Dr. Austad's lab, the concept of how the filled tissue expanders were stored was not public. For one thing, persons having access to the lab would not know the import of the jars until someone explained it to them. (Tr. 1624). Certainly, Dr. Austad did not go out of his way to point it out to visitors. Indeed, Dr. Austad stated that he could not remember anybody inquiring into the specifics of this storage method. (Tr. 1623). Consequently, the court does not find Dr. Austad's experiments to be prior art for purposes of 35 USC 102.

The court observes that even if it were to consider the jars to be prior art, there would be a number of reasons why they do not render Klatt's invention obvious to a person of ordinary skill in the art. First, the jar experi-

ment is not a packaged prosthetic device intended to be implanted. The devices were in jars for testing purposes, not as future implants. Second, the only sterilization Dr. Austad recalled involved sterilizing *explanted* devices, not devices filled and intended for implantation. In addition, the Austad implants were sterilized in open beakers, not the jars or any other "package." (Tr. 1592, 1609-10). In any event, the jars could not maintain sterility, even were it possible to sterilize them. Third, except for one experiment, Dr. Austad frankly admitted that in his "jar experiments", he did not achieve any osmotic balance between the devices and liquid in which they were placed without an initial mass transfer gradient between the device and the liquid in the jar.

B. Level of Ordinary Skill in the Art

Factors that may be considered in determining level of ordinary skill in the art include: 1) the education level of the inventor; 2) type of problems encountered in the art; 3) prior art solutions to those problems; 4) rapidity with which innovations are made; 5) sophistication of the technology; and 6) educational level of active workers in the field. *Orthopedic Equipment Co., Inc. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1381-82 (Fed. Cir. 1983). Not all such factors are present in every case, and one or more may predominate in a particular case.

A second formulation of the person of average skill in the art:

> The person of average skill in the art, under sec. 103, who is the patent law equivalent of the reasonable man in tort law, is neither a genius nor

> an expert, and he is not expected to think entirely in terms of theoretical, physical principles, but is much more likely to be motivated by more mundane considerations, such as the practical functional use of prior art devices.

Ciba-Geigy, Ltd. v. Tenatek, 202 USPQ (BNA) 669, 674 (N.D. Miss. 1978).

Regardless of the formulation used, the important consideration lies in the need to adhere to the statute. The court must hold that an invention would or would not have been obvious, as a whole, when it was made, to a person of "ordinary skill in the art"—not to the judge, or to a layman, or to those skilled in remote arts, or to geniuses in the art at hand. *Environmental Designs v. Union Oil Co. of California*, 713 F.2d 693 (Fed. Cir. 1983).

The relevant time frame is 1983-84. The court finds the testimony of Dr. Goff and Donald Barcan relevant to the resolution of this issue. Dr. Goff testified that the person with ordinary skill in the art would have a technical degree and two or three years of experience in the design of packages for medical devices. (Tr. 1861). On cross examination, he admitted that the most salient training for the packaging field occurs on the job. Similarly, he stated he would not be surprised if there were persons involved in designing packages who had no college education. (Tr. 2021).

Donald Barcan is a packaging engineer called to testify by AMS. He testified that in the 1960s—the infancy of sterile medical device packaging technology—the skill level required to package medical devices was

low. "It might have been a glass syringe, for example, and it went into a box and that box might have been wrapped with tissue." (Tr. 2239). Not surprisingly, persons assigned to package devices usually had no more than a high school education. As the technology associated with medical device packaging became more sophisticated, these persons were not replaced. However, the technical education of incoming packaging personnel began to increase, and through attrition, the educational training of persons skilled in the art began to change. By 1983-84, approximately one third of persons skilled in the art had college degrees. (Tr. 2237-40).

The court also observes that while both William Klatt and Jay Goldberg had technical degrees, neither had any prior experiences in packaging medical devices.

Given the testimony, the court finds that the person of ordinary skill in the art in 1983-84 would have either had a college degree and several years of experience in the medical device packaging field, or would have had no college degree but would have had five to fifteen years experience in the medical device packaging field.[8]

---

[8] The court does not find either Professor Goff or Mr. Barcan themselves to be of ordinary skill in the art; each of them is more highly skilled than the person of ordinary skill. Obviously, that does not mean that the court refuses to consider what they say the person of ordinary skill knows; it only means the court may not look to them as "living examples" of persons with ordinary skill.

C. Differences Between the Prior Art and the Claims at Issue

Mr. Klatt's invention involves a packaged fluid-filled device containing a defined amount of fluid in a semi-permeable housing, and methods of packaging and sterilizing it. The testimony did not disclose that the concept of prefilling and presterilizing a device by the manufacturer existed in the prior art. For example, Banko does not establish this. Professor Goff admitted that Banko does not teach that the lens is to be packaged prefilled and presterilized at the manufacturer. (Tr. 1932-33; *see also* 2259). Nor does the combination of Banko combined with Mazzocco establish this. Neither, according to Dr. Goff, does Naficy teach this particular concept. (Tr. 1934). And the court is simply not convinced that Dr. Austad's patent or jar experiments establishes this. His patent indicates that the implants were intended to be implanted dry; the concept behind his tissue expander was to allow the filling of the device to occur gradually, making the stretching of the tissue less painful. His jar experiments, to the extent they can be considered prior art, were with explanted devices which had filled during their stay in the body of an animal; they were not intended to be reimplanted in that form.

The court also finds there is no prior art showing any packaged medical device containing a defined amount of fluid in a permeable membrane. (Tr. 2026). Dr. Goff admitted that Mr. Klatt designed a product that was filled with a precise amount of fluid by the manufacturer. (Tr. 1936-37). It was then packaged and the package was sterilized. (*Id.*). The critical amount of fluid in the device survived the packaging and sterilization. (*Id.*). Thereaf-

ter, the critical amount of fluid and sterility remained inviolate and survived handling, transport, and lengthy storage so that it was "ready-to-go" during surgery. (*Id.*). And this, Dr. Goff admitted, "no one had ever done before." (Tr. 1937).

Similarly, there is no prior art showing the use of osmotic principles for purposes of packaging and sterilizing any product, much less a medical device. (Tr. 2254). Sutures, as well as packaged bandages, sponges, and soft optical lenses, simply absorb the liquid in the package until they are saturated. There is no need or ability to control the amount of fluid in the materials. (Tr. 1970). In short, these patents merely provide a mechanism by which these items can be kept moist. On the other hand, the Klatt invention involves a device with a critical amount of fluid in a semi-permeable housing, where the fill volume is maintained by controlling the osmolality of the solution inside and outside the device. Analogously, the suture packages do not need to be completely filled with fluid because they are conditioning liquids. Klatt requires substantially complete filling, because air in the enclosure may cause bubbles to permeate the device, causing it to lose critical filling volume. (Tr. 1972-73).

If food packaging and canning is considered prior art, it is no more pertinent than the prior art found in the Campbell patent (Ex. 7) or the Riall patent (Ex. 3) which were considered by the PTO. The canning process described by Dr. Goff included "blanching" the vegetable, placing it in a can, and then closing it. (Tr. 1944-49). In the can, however, the vegetable is saturated with the filling solution and absorbs the fluid around it. There is no way to control how much liquid the food absorbs. (Tr. 1948-53).

Finally, Mr. Klatt's invention was the first time an autoclave process was used with a packaged penile prosthesis. (Tr. 1956).

D. Secondary Considerations

It is jurisprudentially inappropriate to disregard any relevant evidence on any issue in any case, patent cases included. Thus evidence rising out of the "secondary considerations" must always be considered when present, before any determination on the obviousness question is rendered. It is to be considered as part of all the evidence, not just when the court remains in doubt after reviewing the art. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983).

Evidence of secondary considerations may establish that an invention appearing to have been obvious in light of the prior art was not. *Id.* The principal secondary considerations which support findings of non-obviousness are: a) commercial success; b) long-felt but unsolved need; c) failure of others; and d) copying of the claimed invention.

1. Commercial Success

The court finds the Hydroflex was a commercially successful product. From its introduction at the May 1985 AUA meeting, the product enjoyed very good sales, though beginning in 1987 demand for the product has steadily declined. The evidence reflects that in 1985 AMS sold 3,336 Hydroflex units for total dollar sales of $7,665,142.00; in 1986 AMS sold 7,698 Hydroflex units

for total dollar sales of $17,211,040.00; and in 1987 AMS sold 4,809 Hydroflex units for total dollar sales of $13,105,847.00. (Ex. 107).

2. Longfelt But Unsolved Need

Against the backdrop of other patent cases the court has examined, the length of time the urological products industry went without a prefilled and sterile packaged penile prosthesis is not especially long. *See e.g.* 2 D. Chisum, *Patents*, sec. 5.05[1] at 5-398 to 5-399. Approximately eight months elapsed between MEC's introduction of its dry pack Flexi-Flate (October 1984) and AMS's introduction of the Hydroflex (May 1985). There is no evidence of any other company's efforts to prefill a penile prosthesis.

3. Failure of Others and Copying

During the time Mr. Klatt was working on the prefilled Hydroflex, MEC was also working on its prefilled product but without success. Mr. Goldberg then saw the Klatt invention the 1985 AUA meeting and began considering the double pouch system more seriously. In the court's opinion it was no mere coincidence that MEC began to work intensively with the double pouch system shortly after seeing Klatt's invention at the AUA.

The court further observes that, as elaborated at length above, MEC attempted to patent a prefilled product which falls literally within the scope of claims 1-12, 14-15, 18-20, and 20-24 of the Klatt patent.

D. Conclusion on Obviousness

Mr. Klatt's invention is a packaged penile prosthesis and method composed of, respectively, multiple components and multiple steps. All these interact to provide a particular kind of surgical prosthesis with suitable intraoperative characteristics. The invention as a whole is that product, with its packaged form, and its advantages, benefits and properties. It is the combination which is novel and is the subject of the claims of the Klatt patent. (Tr. 1081).

That all elements of an invention may have been old is not unusual, and indeed, irrelevant. Virtually all inventions are combinations and virtually all are combinations of old elements. A court must consider what the prior art as a whole would have suggested to one skilled in the art. *Environmental Designs*, 713 F.2d at 698. The court is unable to accept MEC's contention that the claims of the Klatt patent would have been obvious to a person of ordinary skill in the art at the time of Klatt's invention. It appears to the court that MEC has used the Klatt patent as a roadmap for finding prior art, and had then attempted to combine that prior art with the hindsight afforded by it knowledge of Mr. Klatt's invention; this appeared especially to be true in the case of Dr. Goff's testimony.

For example, MEC's main argument is that Klatt is rendered obvious by combining Banko and Mazzocco. (Tr. 1975). Yet there is nothing in the prior art of record which would invite or suggest to a person of ordinary skill in the art that the two references be combined. That combination can only be made by hindsight reconstruction using Klatt as a roadmap. The only reason Dr. Goff

could give for attempting to combine Banko with Mazzocco was a two pronged "leap of faith" (Tr. 2000) that: 1) Banko would be filled at the manufacturer and be shipped prefilled and sterile; and 2) Mazzocco was the only way of doing it. However, Banko does not disclose how or where his lens is filled or how it is implanted. (Tr. 2246). Even Dr. Goff admitted this. (Tr. 1989). Because there is no suggestion in the art that a Banko lens would be shipped prefilled, there is no incentive or motivation for anyone to combine it with a fluid-filled packaging system such as Mozzocco.

It also appears that there is a reason why those with ordinary skill in the art would not combine Banko and Mozzocco, namely that the Banko and Mozzocco lenses function differently. Mozzocco's lenses do not change shape in the eye. (Tr. 1985; 2247-48). It maintains the same optical properties at all times. On the other hand, the Banko lens is designed to be sutured to muscles in the eye. Then, as the muscles moved, the lens would change its shape and optical properties. (Ex. 854, col. 3; Tr. 1984, 2247-48). The differences are relevant because the point of Mozzocco is to provide a container and fixture whereby the optical properties of a fixed lens can be measured. (Tr. 2247-48; 2261). The Banko lens is not of a type for which the Mozzocco container was designed; the optical properties of the Banko lens are not fixed and change when sutured to the eye muscles. Consequently, there is no motivation for one skilled in the art to combine the two patents.

MEC has not shown anything in the prior art that suggests the particular combination of elements needed to produce Klatt's invention. An invention must be

viewed as a whole, and MEC's prior art does not suggest in any way or motivate one skilled in the art to make the Klatt invention as a whole.

After becoming aware of the issuance of the Klatt patent, MEC engaged in numerous world-wide searches. (Ex. 118). Yet despite all of this extensive searching, MEC has not found any references which describe the unique combination claimed in the Klatt patent. MEC plainly believed that this subject matter was new and nonobvious as evidenced by the filing of its own patent application on the subject matter and failing to cite any of the prior art upon which it now relies to invalidate the Klatt patent.

VIII. Damages

Since the court has determined that the Klatt patent is not invalid for obviousness, and MEC has stipulated that its Flexi-Flate prosthesis would infringe upon such a finding, the court must consider the amount of damages to which AMS is entitled. AMS claims that it is entitled to lost profits for the period of July 1, 1986 (the date the Klatt patent issued) through December 1987 (MEC's noninfringing "vacuum pack" Flexi-Flate entered the market in January 1988) because, but for MEC's infringement, AMS would have made the sales that were made by MEC for its wet pack Flexi-Flate. From January 1988 AMS claims a reasonable royalty, since during this period MEC was principally selling the "vacuum pack" Flexi-Flate (which AMS no longer accuses of infringement), but also continued shipping its remaining inventory of the wet pack Flexi-Flates.

The applicable statutory authority governing the amount of damages is 35 USC 284, which provides in pertinent part:

> Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.

The United States Supreme Court, in interpreting this statute, has defined damages as "compensation for the pecuniary loss the patent owner suffered from the infringement, without regard to the question whether the defendant has gained or lost by its unlawful acts." *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 507, 84 S. Ct. 1526, 12 L. Ed. 2d 457 (1984).

There are two different approaches toward determining the measure of damages in patent infringement cases. *Hartness Int'l v. Simplimatic Engineering Co.*, 819 F.2d 1100, 1112 (Fed. Cir. 1987). The first approach, the lost profits method, is used when the record permits an accurate determination of the patentee's loss. *Hanson v. Alpine Valley Ski Area, Inc.*, 718 F.2d 1075, 1078 (Fed. Cir. 1983). The second approach, employed when actual lost profits cannot be determined, is to award damages on the basis of a reasonable royalty. *Id.*

A. Lost Profits

Pursuant to 35 USC 284, "the general rule for determining the actual damages to a patentee that is itself

producing the patented item is to determine the sales and profits lost to the patentee because of infringement." *Del Mar Avionics v. Quinton Instrument Co.*, 836 F.2d 1320, 1326 (Fed. Cir. 1987). To obtain lost profits, a patent owner must prove causation; that is, that " 'but for' the infringement, the patent owner would have made the sales the infringer made." *Lam, Inc. v. Johns-Manville Corp.*, 718 F.2d 1056, 1065 (Fed. Cir. 1983); *Bio-Rad Laboratories, Inc. v. Nicolet Instrument Corp.*, 739 F.2d 604, 616 (Fed. Cir.), *cert. denied*, 469 U.S. 1038, 105 S. Ct. 516, 83 L. Ed. 2d 405 (1984).

"In proving his damages, the patent owner's burden of proof is not an absolute one, but rather a burden of reasonable probability." *Lam*, 718 F.2d at 1065. The patent owner need only prove that there is a reasonable probability he would have made the infringing sales. *Paper Converting Machine Co. v. Magna-Graphics Corp.*, 745 F.2d 11, 21 (Fed. Cir. 1984). "The determination of damages is not an exact science and 'the amount need not be proven with unerring precision.' The trial court is required to approximate, if necessary, the amount to which the patent owner is entitled." *Del Mar Avionics*, 836 F.2d at 1327. In addition, "the patentee is not obligated to negate every possibility that a purchaser might not have bought the patentee's product instead of the infringing one, or might have foregone the purchase altogether." *Id.* at 1326; *Datascope Corp. v. SMEC, Inc.*, 879 F.2d 820, 826 (Fed. Cir. 1989).

A patent owner may obtain lost profits by meeting the standard set forth in *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152 (6th Cir. 1978):

> To obtain as damages the profits on sales he would have made absent infringement, i.e., the sales made by the infringer, a patent owner must prove: (1) demand for the patented product, (2) absence of acceptable noninfringing substitutes, (3) his manufacturing and marketing capability to exploit the demand, and (4) the amount of profit he would have made.

Id. at 1156. A patentee is not entitled to lost profits if it fails to establish any of the above requirements. *Smithkline Diagnostics v. Helena Laboratories*, 926 F.2d 1161, 1165 (Fed. Cir. 1991). The patent owner must convince the court that it has met each of these elements to a reasonable probability.

MEC does not dispute that there was a demand for the patented product (although it argues that demand did not result from the patent). The court independently finds that there was demand for the patented product, and that demand resulted in substantial part from the characteristics of the patented product. (Tr. 815-16, *see also* MEC Response para. 58). Similarly, MEC does not dispute that AMS had the ability to exploit the demand for the product. The court similarly finds that AMS had the ability to exploit demand for the product. (Tr. 816; Ex. 106).

Central to whether there were "acceptable noninfringing substitutes" for the Hydroflex is the definition of that term. In the recent case *Kaufman Co., Inc. v. Lantech, Inc.*, 926 F.2d 1136 (Fed. Cir. 1991), the Federal Circuit offered the following guidelines for determining if any exist.

> To be deemed acceptable, the alleged acceptable noninfringing substitute must not have a disparately higher price than or possess characteristics significantly different from the patented product.
>
> . . .
>
> "A product lacking the advantages of that patented can hardly be termed a substitute acceptable to the customer who wants those advantages."

Id. at 1142-43 (emphasis in original), *quoting TWM Mfg. Co., Inc. v. Dura Corp.*, 789 F.2d 895, 901 (Fed. Cir. 1986). Nevertheless, "if the realities of the market are that others would likely have captured sales made by the infringer, despite a difference in the products, it follows that the 'but for' test is not met." *SmithKline Diagnostics v. Helena Laboratories*, 926 F.2d 1161, 1166 (Fed. Cir. 1991).

MEC has urged that the court must consider all impotence treatments, including drug therapy, rods, and multi-component inflatables as acceptable noninfringing substitutes for the Hydroflex. Yet the evidence clearly convinces the court otherwise. The salient characteristics of the Hydroflex are that it provided good flaccidity and rigidity without the more invasive surgery necessary to implant the multi-component device.[9] (Tr. 80-81). In

---

[9] MEC suggests that the OmniPhase and DuraPhase mechanical protheses should be classified in the self-contained market. Dacomed first introduced the OmniPhase in August 1986 (Ex. 29), and it had such immediate and major problems that the OmniPhase was withdrawn from the market and then

(continued...)

addition, as between it and the dry pack Flexi-Flate, Hydroflex came to the operating room prefilled and sterile. This was a convenience for the surgeon, but more importantly provided an added margin of safety for the patient, since prefilling with extra clean saline made the valves less prone to jamming, so the implant was less likely to require removal.

The other impotence treatments had their own individual spectrum of properties, benefits and constraints that clearly differentiated one from another making them unacceptable as noninfringing substitutes for the Hydroflex. (Tr. 80-82, 690-92, 726-32). Drug therapy was nonsurgical but was prone to causing priapism, involved sticking needles into the penis, which caused scar tissue to develop. (Tr. 60-61). The rods were inexpensive and had low incidence of malfunction, but were hard to conceal and provided only adequate rigidity for coitus. The multi-component inflatables provided the best concealment and flaccidity but involved more invasive surgery

---

[9] (...continued)
reintroduced in the fall of 1987. (Ex. 29; Tr. 85-86, 228, 562). As noted by Mr. Boeck, the OmniPhase had a history of failure and cosmetic deficiencies. (Tr. 731). The DuraPhase was introduce only in September 1987. These mechanical rods consist of a series of articulating segments with a central cable holding the segments together. (Ex. 24, 28). Their function can be analogized to a gooseneck lamp. Although sometimes classified as "self-contained" devices, they are neither hydraulic nor inflatable, and they do not provide the same properties as Hydroflex or Flexi-Flate. (Tr. 86). In the 1986-87 time period, the OmniPhase and DuraPhase were beset with performance difficulties and had only a minute portion of the prothesis market. (Ex. 82; Tr. 86, 580-83, 729-32).

and had leakage and malfunction problems similar to the dry pack Flexi-Flate.

Further, the realities of the market are not such that other impotence treatments would have captured a significant amount of the sales made by the infringing wet pack Flexi-Flate, despite a difference in the products. In this regard, the court found the testimony of Drs. Bruskewitz and Latham most convincing. Dr. Bruskewitz, an implanting urologist and a highly credible witness, explained how he and other implanters typically explained the options available to patients:

> When it comes to the treatment itself, we have a discussion with the patients about all the various options in some detail. It's often a lengthy discussion, sometimes two discussions in which we spell out the treatment options; psychological therapy, drug injections, vacuum devices, penile implants. And we try and be as detailed as reasonably possible so that the patient is a part of the decision.

(Tr. 63). If the doctor and patient agreed that an implant appeared to be the treatment best suited to the patient, a number of factors specific to devices were discussed, including reliability, concealability, cost, ease of insertion, manual dexterity necessary to operate, and degree of rigidity. (Tr. 90-91). Sometimes after the discussion the patient elected no treatment. (Tr. 77). More often, the patient and doctor would decide upon a device after weighing the advantages and disadvantages of the various implants.

The court finds that those who chose the Hydroflex or the infringing wet pack Flexi-Flate did so after careful deliberation; recognizing the unique set of advantages and disadvantages presented by that particular type of device.[10] They were attracted to it by its good flaccidity and rigidity (better than the rods but not as good as the multicomponent), less invasive surgery (a factor with the multicomponent), and the fact that prefilling made the device less prone to malfunction (a factor with the multicomponent and the dry pack Flexi-Flate). The patients who selected the self-contained inflatable would not have chosen a different type of device had the wet pack Flexi-Flate not been on the market.

---

[10] The court also finds that patients did not have the option of choosing directly between Hydroflex and Flexi-Flate. In performing implant surgery, it was desirable to always have a backup device available. This required hospitals to stock two units in each size for each type of device. The cost of such stocking was very high. As a result, implanters typically offered (and the patient typically had the choice of) only one brand for each type of device. For example, a hospital might stock the MEC Flexi-Rod as its brand of rod, the Mentor device as its brand of multi-component, and the AMS Hydroflex or the MEC Flexi-Flate (but not both) as its brand of self-contained unit. (Tr. 97-99).

As a result of the patient's options being restricted to choosing the *type* of device, as opposed to also choosing the brand within the type, the court rejects MEC's argument that patients would or could choose a self-contained device based on their preference for its operating characteristics. Simply put, the court finds that patients did not have the option of choosing MEC's spontaneous deflation-prone Flexi-Flate over AMS' Hydroflex, which was difficult to deflate, "because it's more natural anyway." (Tr. 888).

The court also found Dr. Latham's testimony helpful on the issue of availability of noninfringing substitutes. Dr. Latham is a professor of economics specializing in quantitative microeconomics, the quantitative study of how individual firms, households and persons decide how to spend their limited resources. Dr. Latham posited that the only way to accurately measure people's preferences for the relative advantages and disadvantages of various products during a historical period, in this case 1985-87, was to examine their purchasing choices, as reflected by market data. (Tr. 845-49). Using this method, Dr. Latham concluded that 1) self-contained inflatables are a submarket within the larger impotence products market (Tr. 822-25); and 2) the dry pack Flexi-Flate was not a serious competitor in this market once AMS was able to overcome the backorder problem with the Hydroflex. (Tr. 797-812, 824, 860-66). Dr. Latham's testimony was very credible, and the court finds that it supports the conclusion that a noninfringing substitute for the Hydroflex did not exist.

After hearing his testimony, observing his demeanor and studying his survey data, the court must to reject the conclusions of MEC's economist, Dr. Lewis Solmon. Dr. Solmon conducted a survey of urologists in 1990 which attempted to demonstrate the "decision process underlying the choices *by urologists* of particular penile prosthetic devices." (Ex. 1015 at 2). The survey, however, is seriously flawed in many respects and as a consequence fails to convince the court of the availability of acceptable substitutes in the penile implant market in 1986-87.

Flaws in the survey include the following. First, the court has serious doubts about whether it is possible to survey in 1990 the preferences of persons in 1986-87 with any degree of accuracy. In this regard, the court chooses to credit Dr. Latham's assertion that it is poor technique for an economist to utilize a survey to obtain the preferences of consumers. Second, the survey fails to address the reality that the patient and the physician choose the particular type of implant together. As was clear from the testimony of Dr. Bruskewitz and the other urologists, the patient had substantial input into which device was appropriate for his lifestyle. Third, to the extent that it would be appropriate to study urologists, Dr. Solmon did not study the appropriate population of urologists, namely actual implanters of penile protheses active in 1986-87. (Tr. 2157-62, 2173-74). Fourth, the response rate to the survey of about six percent was well below acceptable limits, and no post-survey attempts were made to determine how representative the respondents were of the total relevant population. (Tr. 2155, 2165-77, 2180-82). Fifth, the terms used and the questions asked were not pretested and were in many instances confusing, overlapping and uncertain in meaning, particularly regarding terms like "consider" and "packaging." (Tr. 2154, 2184-97; see also 1806-08, 121). Sixth, Dr. Solmon was inexperienced in conducting surveys of this nature. (Tr. 2156). Seventh, no evidence was presented regarding the mailing, receipt, coding or accuracy of the data. (Tr. 2156). Eighth, the survey was mailed to the same population twice, with no care taken to avoid multiple responses from the same doctor. (Tr. 2182-83).

Finally, the court turns to the question of whether AMS has proved the amount of profit it would have made on each of the Hydroflex units it would have sold but for the sale of the infringing Flexi-Flate. The court concludes, based on the lengthy testimony of Dr. Latham, the deposition testimony of AMS controller Robin Cleveland, and documents prepared by AMS, that AMS would have obtained incremental income of $2,072 for every additional unit of Hydroflex that it would have sold in the United States, and $888 for every international sale during the period July 1, 1986 to December 31, 1986. The court further finds that during 1987, the AMS would have enjoyed an incremental income of $2,266 for every additional Hydroflex it sold in the United States and $832 for every international sale. (Ex. 100, 112; Tr. 812, 817-21, 836, 918-99). MEC has presented no evidence to suggest that AMS' incremental profit calculations are incorrect. Thus, the lost profits to which AMS is entitled may be calculated by multiplying the per unit incremental profit times the number of infringing sales made during the relevant time period.

B. Patent Marking

MEC claims AMS may only recover limited damages for two reasons. First, MEC claims AMS failed to mark the Hydroflex with the word "patented" until long after the patent issued. In addition, MEC claims that AMS never provided "notice" of the claimed infringement until this lawsuit was filed on October 28, 1987. As a result, MEC claims it is only liable for damages from the date of filing.

The Patent Act imposes on patent owners a duty to mark patented articles. 5 D. Chisum, *Patents*, sec. 20.03[7][c] at p.20-249. However, where a patent claims only a method (as opposed to a product, or a method and a product) there is no duty to mark. *Bandag, Inc. v. Gerrard Tire Co., Inc.*, 704 F.2d 1578, 1581 (Fed. Cir. 1983) *citing Wine Railway Appliance Co. v. Enterprise Railway Equipment Co.*, 297 U.S. 387, 56 S. Ct. 528, 80 L. Ed. 736 (1936). This is not surprising since one cannot mark an abstraction. A somewhat more problematic question is whether there is a duty to mark when the patent contains both product and method claims. In *Devices for Medicine v. Boehl*, 822 F.2d 1062 (Fed. Cir. 1987), the court indicates that where there are both product and method claims being claimed infringed, the patentee must mark the product.[11] This is consistent

---

[11] The *Devices for Medicine* court stated:

> In *Bandag*, and in *Hanson [v. Alpine Valley Ski Area, Inc.*, 718 F.2d 1075, 1083 (Fed. Cir. 1983)], this court specifically noted a distinction between cases in which only method claims are asserted to have been infringed and cases like the present case, where [patentee] alleged infringement of all its apparatus and method claims. . . . The claimed method is the use of the product. Having sold the product unmarked, [patentee] could hardly maintain entitlement to damages for it use by a purchaser uninformed that such use would violate [patentee's] method patent.

822 F.2d at 1066. AMS argues that this case is inapposite, since a method of *using* a product (claimed in *Devices for Medicine*) is different than a method of making a product (which Klatt claims). Nevertheless, while the facts of the cases (making versus using) are different, the rationale behind the

(continued...)

with the spirit of the patent marking statute, requiring the patentee to put the world on notice of his patent if he is to collect damages.[12] It makes good sense to require patentees to mark their products even if the patent also alleges method claims; a patentee should not be relieved of its duty to alert the public that its product is patented simply because the patent also alleges method claims. Consequently, the court concludes that if AMS is to collect damages, it must have marked the Hydroflex, notwithstanding that the Klatt patent also contains method claims.

"The person under the duty to mark must so mark *all* patented articles made and sold. Thus omission from any substantial number constitutes noncompliance." 5 D. Chisum, *Patents*, sec. 20.03[7][c][iii] at p.20-258 (emphasis in original). AMS did not begin marking Hydroflex

---

[11] (...continued)
marking statute remains the same: to the extent there is a tangible item to mark, a party is under an obligation to warn the world of his patent. He is relieved of this duty only when there is nothing to mark.

[12] "The Patent Act imposes a duty to mark on patent owners. The purpose of the statutory duty is to prevent patent owners from deceiving the public by distributing unmarked (and hence apparently copyable) articles which are in fact covered by a patent. . . . There is no duty to mark . . . patented processes. . . . The only consequence of failure to mark is a limitation on recoverable damages for patent infringement. If the patent owner . . . fails to mark as required, the patent owner may only recover damages for acts occurring after the infringer received notice charging infringement. The filing of suit for infringement constitutes notice." 5 D. Chisum, *Patents*, sec. 20.03[7][c] at p.20-249.

with the Klatt patent number until approximately three and one half months after the patent issued. (Tr. 521). As a result, MEC claims AMS cannot recover any damages before the filing of the complaint unless MEC received notice that it was infringing. AMS on the other hand claims 35 USC 287 "does not require marking or notice within any specific period after issue as a condition for recovery of damages for infringement, and the statute must be interpreted to provide some reasonable leeway or grace period to effect a label change and patent marking."

The court concludes that AMS is obliged to have marked all Hydroflexes subsequent to issue of the patent, except that it is allowed a relatively small number to be shipped unmarked as it readies the marking process. 5 D. Chisum, *Patents*, sec. 20.03[7][c][iii] n. 109[13] and 20.03[7][c][iv] & n.133. AMS did not even begin the internal process for marking Hydroflex until two months after the patent issued on July 1, 1986, and it did not begin shipping marked Hydroflexes until October 15, 1986, three and one half months after the Klatt patent issued. (Tr. 521). By the court's calculation, during that three and a half month time span 1,939 Hydroflex units were shipped without the patent marking. (Ex. 109). Further analysis of this same record of shipments discloses

---

[13] Chisum makes note of *Hazeltine Corp. v. Radio Corp. of America*, 20 F. Supp. 668 (S.D.N.Y. 1937) which states: "It is . . . explicit that there must be marking of every patented article sold—subject, of course, to the implied exception of de minimus, as, for example, failure by mistake to mark a few articles in hundreds of thousands made and sold might not, I venture, be ground for refusing an accounting."

that during the period July 1, 1986 through December 31, 1986 the 1,939 unmarked units shipped exceed the 1,381 marked units shipped by 558 units. Moreover, if the 4,287 units shipped between January and the end of October 1987 are combined with the 3,320 units shipped in 1986, the percentage of unmarked units still exceeds 25 percent—hardly insignificant. AMS could have easily complied with the marking requirement simultaneous with the issuance of the Klatt patent by affixing an appropriate label on the outer packaging of Hydroflex units in its inventory. The court concludes that AMS plainly did not comply with the patent marking statute.[14]

35 USC 287 provides that "in the event of failure to so mark" as specified, no damages may be recovered against an infringer "except on proof that the infringer was notified of the infringement and continued to infringe thereafter." 5 D. Chisum, *Patents*, sec. 20.03[7][c][iv]. "In applying the notice provision, the cases generally require that the patent owner give specific and actual notice to the accused infringer charging infringement of the patent in question. It is not normally sufficient that the infringer has actual knowledge of the patent." *Id.*; *see also Devices for Medicine v. Boehl*, 822 F.2d 1062, 1066-67 (Fed. Cir. 1987) ("Absent notice, [infringer's] 'knowledge of the

---

[14] "It is not the number of articles seen by the defendant which is controlling on an issue of marking . . . but whether the patentee performed his statutory duty which was a prerequisite to his in rem notice to the world, and hence, failing personal notice to the infringing defendant, a condition precedent to his cause of action for damages or accounting for profits." *Hazeltine Corp. v. Radio Corp. of America*, 20 F. Supp. 668 (S.D.N.Y. 1937).

patents' is irrelevant. Section 287 requires 'proof that the infringer was *notified of the infringement*' (emphasis ours).").

In the present case, it appears that MEC was aware of the Klatt patent soon after it issued. Thad Kryshak, MEC's local patent counsel, testified he learned of it from the Official Gazette some weeks after it issued. (Tr. 1371). Stuart Krieger testified that he was already aware of Klatt when James Elacqua called him about it a month after it issued. (Tr. 1766-68). Nevertheless, it also appears that MEC was not specifically notified of infringement until some two and one-half months later. Although Elacqua called Kryshak, Elacqua never accused MEC of infringement. (Tr. 1369-70; 1637). Similarly, Elacqua never told Krieger that AMS was accusing MEC of infringement. (Tr. 1762, 1767).

AMS would like the court to conclude MEC had notice because MEC was aware of the Klatt patent. But awareness is insufficient; AMS is only entitled to damages commencing from the time it specifically accused MEC of infringement. This it did not do until October 28, 1987, at which time the complaint was filed (but not served) and MEC was notified of the filing. (Tr. 1659-60). Clearly, AMS felt it advantageous to withhold making an explicit accusation of infringement to prevent a declaratory judgment suit from being filed by MEC; it bought AMS valuable time to attempt to settle the case without resorting to litigation. (Tr. 1106, 2408). This was a calculated risk; the parties still ended up in litigation, and as a result AMS' damages are significantly reduced as a consequence of its failure to give notice of infringement.

Thus, AMS' damages for lost profits are limited to November and December 1987 and appropriately determined as follows:

MEC's Total Unit Sales, all filled Flexi-Flates (Ex. 109).

	Domestic	International
November 1987	210	3
December 1987	181	22
Total	391	25

AMS 1987 Incremental Profit—Hydroflex Unit (Ex. 100).

Domestic Sales	$2,266.00
International Sales	832.00
391 x $2,266.00 =	$886,006.00
25 x 832.00 =	20,800.00
AMS Total Lost Profits	$906,806.00

C. Reasonable Royalty

The court next considers two related issues concerning reasonable royalty. First, AMS contends that it is entitled to a reasonable royalty commencing January 1988. From that time forward, MEC was principally selling the vacuum pack Flexi-Flate, but was also selling out its remaining stock of the wet pack Flexi-Flate; AMS claims it is entitled to a royalty of 25 percent of the net sales price for each of the wet packs sold. Second, in order that the record be complete, the court will also discuss what its findings on reasonable royalty would have been had it not found that AMS was entitled to lost profits.

The legal authority relevant to the two issues is the same. If a court finds that damages should not be measured by lost profits, then it must find that the patent owner is entitled to a reasonable royalty under 35 USC 284. *Panduit*, 575 F.2d at 1157. A reasonable royalty is "the floor below which damages shall not fall." *Stickle v. Heublein, Inc.*, 716 F.2d 1550, 1561 (Fed. Cir. 1983). An award based on a reasonable royalty after infringement "must be at least a close approximation of what would be 'adequate to compensate' for the 'use made of the invention by the infringer.' " *Fromson v. Western Litho Plate and Supply Co.*, 853 F.2d 1568, 1575 (Fed. Cir. 1988). The fictional negotiation is as of a date when infringement by the defendant began and is based on the assumption that the patent was valid. 5 D. Chisum, *Patents*, sec. 20.03[3][a].

The reasonable royalty analysis creates a hypothetical licensing negotiation between a willing licensor and a willing licensee and determines the reasonable royalty for the parties. *Stickle*, 716 F.2d at 1561. In determining the result of such a hypothetical negotiation, the court may consider: 1) prior existing licenses, if any, under the patent; 2) industry custom and licenses on comparable patents; 3) the patent owner's licensing policy and the relation between the parties; 4) the infringer's anticipated profits; 5) comparative utility and noninfringing alternatives; 6) collateral benefits and convoyed sales; 7) improvements, small parts and apportionment; 8) state of development and commercial success; and 9) duration of patent. 5 D. Chisum, *Patents*, sec. 20.03[3][b]; *see also Panduit Corp. v. Stahlin Bros. Fibre Works*, 575 F.2d 1152 (6th Cir. 1978); *Georgia-Pacific Corp. v. United*

States Plywood Corp., 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), *modified and aff'd*, 446 F.2d 295 (2d Cir. 1971).

In addition, the court may utilize expert testimony to aid its determination. *Trell v. Marlee Electronics Corp.*, 912 F.2d 1443, 1446 (Fed. Cir. 1990). Similarly, the court is permitted, and often required, to consider events and facts that occurred after the infringement, and could not have been known to or predicted by the hypothesized negotiators. *Fromson v. Western Litho Plate and Supply Co.*, 853 F.2d 1568, 1575 (Fed. Cir. 1988). The court is not limited to selecting one or the other of the specific royalty figures urged by counsel as reasonable. *Smith-Kline Diagnostics, Inc. v. Helena Laboratories Corp.*, 926 F.2d 1161, 1167-68 (Fed. Cir. 1991). The determination of a reasonable royalty must be based upon the entirety of the evidence and the court is free to, and indeed must, reject royalty figures proffered by the litigants where the record as a whole leads the court to a different figure. *Id.*

The court will first examine what a reasonable royalty would be in this case. The court takes the following into consideration in arriving at a reasonable royalty:

First, there is no established royalty rate for the Klatt patent. There were, however, royalties negotiated between the parties with respect to other aspects of penile prosthesis products. While these licenses are not on Klatt but on interferences, and thus accorded lesser weight by the court, they are indicative of the "ballpark" for licenses on penile prostheses, and therefore relevant. (Exs. 122, 123, 124A).

Second, AMS had little incentive to license the Klatt patent. AMS was using the patent, and had the manufacturing capacity to meet demand for prefilled self-contained protheses. By granting MEC a license, AMS would have been assisting the competition in a highly competitive market, and in a submarket where it clearly was gaining an edge.

Third, MEC had an immediate need to get a prefilled and sterile self-contained prosthesis into the market. In the court's opinion, however, this does not mean that MEC would have paid any price AMS sought for a license under Klatt. Certainly, Klatt was available and this was an incentive to MEC, since getting into the market was important. However, in an arms length transaction, MEC would not have paid more for Klatt than it was worth in increased profits to the company; no reasonable business person would. If the price of the license was too high, MEC would have attempted to design around Klatt by continuing to develop a vacuum package.

Fourth, the opinion of others knowledgeable about royalties in the industry are relevant. Dr. Latham, AMS' economist, testified that an appropriate royalty would be around 35 percent of the selling price. (Tr. 837-39). The court is inclined to give somewhat lesser weight to Dr. Latham's estimate of a reasonable royalty because he has no experience actually negotiating them. MEC called Lawrence Swaton, a health care industry consultant who has negotiated licenses. He said he would pay a royalty of less than one percent for the Klatt patent. (Tr. 2050). He also said the highest royalty he ever personally encountered was eight percent. (Tr. 2053).

Determining a reasonable royalty from a hypothetical negotiation is not easy; the process is truly artificial.[15] Obviously, since the court must arrive at a figure, it cannot determine that negotiations broke off—that the seller refused to go lower and the buyer refused to go higher. Basically, the court must pretend these parties are locked in room and forced to remain there until they arrive at a figure. Given the evidence, it is reasonable to conclude that if locked in a room, the parties would have arrived at a figure somewhere between those suggested by Dr. Latham and Mr. Swaton.

In the court's view, the one percent royalty posited by Mr. Swaton does not sufficiently take into account MEC's immediate need to get the prefilled prosthesis into the marketplace. MEC would have been willing to pay more than one percent because it would be cheaper than de-

---

[15] In an especially thoughtful opinion several years ago, Chief Judge Markey observed that determining a fair and reasonable royalty often involves "more the talents of a conjurer than a judge." *Fromson*, 853 F.2d at 1574. He observed, and this court agrees, that creating hypothetical negotiations is an imperfect method for determining a reasonable royalty. It "requires a court to imagine what warring parties would have agreed to as willing negotiators." *Id.* at 1575.

Similarly, using this method risks creating the perception that infringing patents is a no-risk proposition, with the sole penalty consisting of forcing the infringer to pay the royalty it would have paid in the first place. The court agrees with Chief Judge Markey that the proper method of recognizing that an infringer is not like a willing licensee is to consider increased damages under section 284 for willfulness or for attorney's fees under section 285, rather than artificially inflating the royalty rate, as AMS seems to suggest. *Id.* at 1576.

veloping an alternative packaging technology. And more importantly, paying the royalty would get MEC into the market more quickly. By the same token, the 35 percent royalty opined by Dr. Latham does not take sufficient account of MEC's need to make a profit. Also, the court finds that while Dr. Latham is a good economist and credible witness, his opinion on this subject is entitled to lesser weight because he has no experience actually negotiating licenses. The court is of the opinion that MEC would have refused to pay a royalty of 35 percent, but would have been willing to pay something lower.

After closely examining all the evidence submitted by the parties, the court concludes that the hypothetical negotiation would have resulted in a license of the Klatt patent for 8 percent of the net selling price of the wet pack Flexi-Flate.

The court next examines AMS' claim for post-January 1, 1988 damages. AMS claims it is entitled to a 25 percent royalty for wet packs sold after January 1, 1988 because this is a "conservative" estimate of the amount MEC saved by not having to repackage the remaining wet packs in vacuum packaging. As justification for its royalty number, AMS points to MEC's policy of allowing buyers to return inadvertently opened wet packs and receive a 65 percent credit. (Ex. 37 at 5; Tr. 839-41). Apparently, the inference AMS wishes the court to draw is that the returned prostheses were repackaged and resold. According to AMS, since MEC was willing to credit its customers for 65 percent of the purchase price for inadvertently opened packages, 35 percent must represent the value of the packaging. As a result, says AMS, the amount MEC saved by not repacking wet packs was 35

percent. AMS claims a 25 percent royalty, as opposed to 35 percent, "to allow for some conservatism in the estimate of total damages." (Tr. 841).

The court is disinclined to follow the tenuous logic of this argument. First, without more, the court cannot say that 35 percent represents MEC's packaging value. Certainly there was little, if any, evidence to support this contention. The return program may simply have been a marketing tool bearing no relation to the cost of packaging or repackaging. Similarly, and more importantly, a reasonable royalty should not be gauged by an estimate of the infringer's savings, but by what would be negotiated in a hypothetical arm's length transaction between the parties. Consequently, the court finds and concludes that to the extent AMS is entitled to a reasonable royalty, whether post-January 1988 or in lieu of lost profits, the figure must bear a reasonable relationship to what the parties would have negotiated, in this case 8 percent of the net sales price.

For purposes of assessing damages the post January 1, 1988 royalty amounts to $46,264.24 (Total 1988 net wet pack Flexi-Flate sales of $578,303 x .08 = $46,264.24).

D. Willfulness

The court next turns to AMS' contention that it is entitled to triple damages because MEC willfully infringed its patent. To establish willful infringement, a plaintiff must prove by clear and convincing evidence that the defendant acted with no reasonable basis for believing it had the right to do so. *State Industries Inc. v. Mor-Flo*

Industries, Inc., 883 F.2d 1573, 1581 (Fed. Cir. 1989). The Court of Appeals for the Federal Circuit has emphasized that district courts are not to look to any one factor as dispositive, but instead are to look to the "totality of the circumstances." *E.g., State Industries*, 883 F.2d at 1581 *citing E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1440 (Fed. Cir. 1988); *Studiengesellschaft Kohle mbH v. Dart Industries*, 862 F.2d 1564, 1573 (Fed. Cir. 1988). Among the factors the court should consider are: 1) whether the infringer, when he knew of the other's patent protection, investigated the scope of the patent and formed a good faith belief that it was invalid or not infringed; 2) whether the infringer deliberately copied the ideas or design of another; and 3) the infringer's behavior as a party to the litigation. *Bott v. Four Star Corp.*, 807 F.2d 1567, 1572 (Fed. Cir. 1986).

1. Krieger Opinion

Stuart Krieger testified in person and by deposition during the trial. Mr. Krieger remains a senior patent attorney at Bristol Meyers' headquarters in New York City. MEC is a subsidiary of Bristol Meyers, and Krieger was in charge of MEC's patent matters. When the Klatt patent issued on July 1, 1986, he had been a patent attorney for about ten years. (Tr. 592).

In late July 1986, Krieger learned of Klatt through his own efforts. (Ex. 118). He became aware of it because he had a patent office subscription for the class of patents in which Klatt appeared. (Tr. 596; 1059). Upon discovering it, he immediately contacted Garry Carter, MEC vice president for scientific affairs. (Ex. 118; Tr.

1203). He then contacted Thad Kryshak, who had prosecuted the Goldberg patent, because he presumably knew something about the art. (*Id.*; Tr. 1071). During the rest of the month of July and into late August, Krieger authorized a number of patent validity searches, including searches in the United States (by Sherman & Shalloway), Japan (by Aoki & Associates), and Britain (by Mathes & Squire), (Ex. 118; Tr. 1071-72), and several in West Germany. (Tr. 602-03, 609, 611). He also ordered an in house computer validity search done on the Klatt patent.[16] (Tr. 613). Similarly, by the end of August, Krieger reviewed the Klatt prosecution history and file wrapper. He testified he understood the nature of the prior art, as well as the arguments of prosecuting counsel and positions taken by the examiner in connection with the prosecution. (Tr. 625-26).

Krieger says he took into consideration his study of the Klatt prosecution, a physical Hydroflex sample, the search results, and conversations with MEC research and development people. (Tr. 634-39). He alleges, however, that he is unable to recall any details of the searches that were performed after he became aware of the Klatt patent. (Tr. 605-06, 609-10, 613-14). He could not remember what references he relied upon in reaching his opinion. (Tr. 640-44). He could not recall even the most general details of technical teachings in the references that he found most pertinent, nor how the relied upon references fit together to invalidate Klatt. (Tr. 643-44).

---

[16] Unfortunately, the results of the searches are not part of the record, since MEC asserts the attorney-client/work product privileges as to such matters.

He could not identify any of the logic he relied upon in forming his opinion other than: "If you combine the teachings of this reference with those of another reference, it renders the Klatt patent and all its claims invalid." (Tr. 642). However, Mr. Krieger did remember that, based on his study, he concluded that Klatt was invalid for obviousness. (Tr. 639).

At the end of August or the beginning of September 1986, Krieger informed Robert Helbling, the president of MEC, of his opinion that the Klatt patent was invalid for obviousness. (Tr. 645, 647, 1763). The opinion was rendered orally, either in person or over the phone. (Tr. 644, 647). Krieger states that it was his normal practice to provide opinions to Helbling orally, and in layman's terms, because Helbling has no understanding of patent law. (Tr. 648; 1761). According to Helbling, Krieger told him that the wet pack Flexi-Flate fell literally with the scope of the Klatt claims, and discussed intraocular lenses and mammary protheses with him. (Tr. 1151, 1153). However, Helbling basically relied on his patent counsel's bottom line assessment, and was uninterested in the rationale used to reach the conclusion: "[Krieger] doesn't usually go into a lot of detail on his opinions with me any more than my finance individual would go into detail with me on how he decides to calculate depreciation." (Tr. 1154).

In order for the court to be able to find that the defendant undertook a good faith effort to determine the validity of the patent, the court must be able to ascertain that defendant undertook the necessary analysis. Standing alone the fact that Mr. Krieger rendered his opinion orally is of little consequence. A well-supported oral

opinion can be just as indicative of good faith as a written one. The advantage of a written opinion, however, is that the court can more easily examine the thought process by which the conclusion was derived. With an oral opinion, the court is left to draw inferences from the testimony and source documents of record.

Robert Helbling indicated that the opinion he received was "conclusory," did not indicate a search for prior art had been made, identified no prior art, did not indicate how the art relied upon was more pertinent that the art considered by the PTO, and did not discuss any of the secondary considerations of patentability. (Tr. 1153-59). He stated that he was uninterested in any of the premises used to arrive at the conclusion the patent was invalid. As a layman, this is perhaps not surprising. But even if Mr. Helbling delegated the determination of validity/invalidity to his attorney, the court still must determine whether the defendant had a good faith belief that the Klatt patent was invalid. MEC may not employ a "clean heart, empty head" philosophy by divorcing itself from the advice of its counsel. Thus, the court must examine, as part of the totality of the circumstances, whether the defendant's attorney had a good faith belief in the invalidity of the Klatt patent.

The court has endeavored to ascertain how Mr. Krieger arrived at his conclusion, but without much success. Mr. Krieger's inability to recall, selectively it seemed, many of the salient details surrounding his rendering of the oral opinion of invalidity is indeed troubling. After hearing his in-court testimony and portions of his deposition read, and observing his demeanor, the court is left with the firm impression that Mr. Krieger

knew more than he was telling, and that what he knew was against the interests of MEC.

In addition, the court was unable to examine much of the relevant documentary evidence, owing to MEC's assertion of the attorney client privilege to numerous documents relevant to the issue of willfulness. Thus, the court was without the benefit of what thought went into Mr. Krieger's opinion, and whether Mr. Krieger found pertinent patents or documents not considered by the examiner. The court concludes that these documents were not released because they indicate a lack of support for invalidity. *Cf. Fromson v. Western Litho Plate & Supply Co.*, 853 F.2d 1568, 1572-73 (Fed. Cir. 1988) ("Where the infringer fails to introduce an exculpatory opinion of counsel at trial, a court must be free to infer that either no opinion was obtained or, if an opinion were obtained, it was contrary to the infringer's desire to initiate or continue use of the patentee's invention.")

The record does not disclose that Mr. Krieger found art more pertinent than that cited to the examiner. Nor is there any indication that he considered the secondary considerations. What the record does reflect is a massive failure of memory on the part of Mr. Krieger. As a consequence the court is left to conclude that Mr. Krieger's opinion of invalidity lacked sufficient support to constitute an authoritative opinion upon which good faith reliance on invalidity may be founded. *Bott v. Four Star Corp.*, 807 F.2d 1567, 1572 (Fed. Cir. 1986).

2. Smith Opinion

In early November 1987, Krieger requested that outside counsel render an opinion on the validity of Klatt.

(Ex. 118; Tr. 650, 1751). His request came after AMS had filed (but not served) the original complaint in this action. He stated he was not aware of the commencement of litigation until February 1988 when Pfizer (AMS' parent) provided Bristol Meyers with a courtesy copy of the complaint. (Tr. 1764).

Krieger called Jamie Smith of Allegretti & Witcoff to undertake the evaluation. (Tr. 1706). She conducted what in the court's opinion was a thorough evaluation of the validity of the patent. (Tr. 1707-60).[17] She concluded that the claims of the patent would be ruled invalid as obvious over prior art, and that in her opinion Dr. Austad's work with tissue expanders was so close that a "very decent argument" for anticipation could be made with respect to some of the broad claims. (Tr. 1741). She informed Krieger of this conclusion over the telephone in December 1987 or January 1988. (Tr. 1740). She said "he was very relieved and he said that was the opinion that he had reached and the opinion he had give orally some time ago." (Tr. 1741). Krieger asked her to reduce her opinion to writing, which was completed as of February 24, 1988. (Ex. 711; Tr. 1741-42).

In the court's view Ms. Smith's opinion arrived too late to be reasonably relied upon by MEC. It was not rendered until MEC had been infringing the Klatt patent for almost twenty months. The opinion was written after MEC had stopped making the wet pack, and after suit

---

[17] During her testimony, she also stated that Krieger turned up the intraocular lens references which she relied upon and which proved to be a cornerstone of MEC's obviousness defense. (Tr. 1721-22, 1741).

had been filed in the case. In addition, the opinion relies on art which is the same as or no more pertinent than that considered by the PTO. Moreover, Mr. Helbling had no knowledge of the Smith opinion in 1986-87 and testified that he relied only on Mr. Krieger's opinion. (Tr. 1165-66).

3. Copying

Finally, the court finds relevant to the willfulness calculus the actions of Mr. Goldberg. The record amply demonstrates that MEC was working, albeit without much success, on a pouch and tube configuration prior to Goldberg seeing AMS' product at the 1985 AUA convention. There can be little question that seeing AMS' product at the convention, and later in hand, provided much of the impetus for what turned out to be the final Flexi-Flate wet pack product. Accordingly, the court finds MEC copied, to a large extent, AMS' Hydroflex packaging design.

After carefully scrutinizing the evidence, under the totality of the circumstances, the court finds by clear and convincing evidence that MEC willfully infringed the Klatt patent.

4. Amount of Increase

The patent remedy statute, 35 USC 284, authorizes the court to "increase the damages *up to* three times the amount found or assessed." (court's emphasis). If the infringer's conduct warrants an exemplary award, the amount should be tempered by the goals of deterring and

punishing the willful infringer on the one hand, and of fully compensating but not unjustly enriching the patent owner on the other. 5 D. Chisum, *Patents*, 20.03[4][b] at 20.174.3, 20-177.

The court finds that the goals of deterrence and avoidance of unjust enrichment are met by enhancing plaintiff's compensatory award by a multiplier of 1.5.

5. Attorney Fees

35 USC 285 authorizes the court "in exceptional cases" to award "reasonable attorney fees" to the prevailing party. The award of such fees is discretionary with the trial court, but such discretion may only be exercised upon a specific finding of exceptional circumstances. 5 D. Chisum, *Patents*, sec. 20.03[4][c]. Often, when a court makes a finding of willful infringement, it will also find that the case is exceptional and award attorney fees.

In the present case, however, the court finds that the better exercise of discretion is to deny attorney fees despite the finding of willfulness. In the court's opinion, whether plaintiff's evidence of willfulness reached the threshold of "clear and convincing" was a close call. Ultimately, the court decided it did, but considerable thought had to be given to that finding before it was made. Basically, there was a lack of evidence of good faith rather than explicit evidence of bad faith. Stuart Krieger was unable to recall the basis for his oral opinion. Robert Helbling was uninterested in anything but the bottom-line opinion. There was no available documentary evidence to establish good faith.

In addition, this was a hard fought case in which neither side gave an inch. Both parties spent a great deal of money prosecuting and defending the case. MEC spent over a million dollars on attorney fees, and there is no reason to believe AMS spent anything less, although AMS' chairman Robert Buuck, had no first hand knowledge as to how much AMS or its parent had expended in legal fees. (Tr. 2389).[18] To be sure, Mr. Buuck is no stranger to the high costs associated with litigation, a fact further evidenced by his conversations with the president of MEC in 1985 in reference to another patent dispute wherein he stated that the parties should settle their differences ". . . so that we would not have to be

---

[18] The court had the following colloquy with Mr. Buuck:

> THE COURT: There has been testimony that has come out during the course of this trial MEC has expended more than a million dollars in fees to defend this case. My question to you, sir, are you in a position to disclose to the Court the amount of money that AMS has paid for outside legal counsel to prosecute this case?
>
> THE WITNESS: No, sir, I don't have that information. I would disclose it if I had it. I do not have that information. Part of that is because of the process by which we budget—or reimburse legal fees through our parent company, Pfizer. I don't have access to all that.
>
> THE COURT: And it is of no personal concern to you as chairman?
>
> THE WITNESS: Oh, yes, it is a concern, sir. I mean, I can't tell you how much it troubles me that these kinds of expenses and proceedings go on. It is a great concern. But I don't know the specific number.

(Tr. 2389-90).

involved in legal court battles where only the attorneys win" (Tr. 1178)—truly a self-fulfilled prophecy when applied to this case.

AMS played hardball just like MEC did; for one party to say the other "started it" would be like the pot calling the kettle black. Some examples–

> James Elacqua of AMS called MEC's patent attorneys and brought Klatt to their attention, but stopped short of alleging infringement. AMS later attempted to make this telephone call into something more, an "implicit" allegation of infringement, when the need arose due to the patent marking problem. (Tr. 1103, 1767).
>
> AMS filed the original complaint in this matter in October 1987, but did not serve it, until December 1987. An amended complaint was served in February 1988.
>
> AMS refused to admit that MEC's vacuum pack did not infringe the Klatt patent until it was ordered to do so by the court.
>
> Lead counsel for both parties kept the court busy with numerous discovery disputes—the type best reserved for the sandbox spats of children rather than advocacy in a federal court.
>
> Tensions during this trial were higher than is usual. Remarks made during the trial were more like brickbats thrown at opposing counsel than advocacy.
>
> The parties are familiar litigation opponents, having litigated cases in the past. Likewise, they

> appear to be litigation opponents for the foreseeable future.[19]

Given the closeness of the willfulness issue, the conduct of the parties, and the totality of the circumstances, the court finds that consistent with the American rule the better exercise of discretion requires that each party bear its own attorney fees.

IX. MEC Counterclaims

MEC has asserted counterclaims. The first counterclaim is for declaratory judgment of invalidity and non-infringement. In light of the court's earlier finding upholding the validity of the Klatt patent, there is no need to address this issue further.

The second counterclaim is for an alleged breach of warranty. A warranty is an assurance by one party to a contract of the existence of a fact upon which the other party may rely. It is intended to relieve the promisee of any duty to ascertain the fact for himself, and amounts to a promise to indemnify the promisee for any loss if the fact warranted proves untrue. *Dittman v. Nagel*, 43 Wis. 2d 155, 160, 168 N.W.2d 190, 193 (1969).[20]

---

[19] MEC has filed an action against AMS in the United States District Court for the District of Minnesota, Case No. 3-91-CV-348 alleging infringement of three MEC patents by AMS' making and selling of its revised self-contained inflatable penile prothesis. (Ex. 181).

[20] The parties agree Wisconsin law controls on the counterclaims.

MEC claims AMS breached warranties contained in agreements the parties negotiated to resolve two interferences and an arbitration. One of the agreements contained language to the effect that the parties "warranted that there are no other issued patents, nor any pending applications for letters patent . . . with respect to any device disclosed to the warranting party by the other party which would result in any infringement or other potential litigation issue." MEC states the Klatt patent application was pending during the negotiation and execution of the agreements, and that AMS' failure to disclose Klatt breached the agreements' warranties.

There are several considerations which enter into whether there was a warranty which covered the disclosure of Klatt or not. First, the court must consider whether the contract is ambiguous. Words or phrases in a contract are ambiguous when they are susceptible of more than one meaning. *Patti v. Western Machine Co.*, 72 Wis. 2d 348, 351-52, 241 N.W.2d 158, 160 (1976). Absent ambiguity within the document, the construction of a contract presents a question of law. *Lakeshore Commercial Finance Corp. v. Drobac*, 107 Wis. 2d 445, 457, 319 N.W.2d 839, 842 (1982). An agreement should be given a reasonable meaning so that no part of the contract is surplusage. *Koenings v. Joseph Schlitz Brewing Co.*, 126 Wis. 2d 349, 366, 377 N.W.2d 593, 602 (1985) (provisions of a contract read together).

MEC concentrates on the language in paragraph 17.8 of the Hakky agreement (Ex. 122), and to a lesser extent, on paragraph 19.8 of the Finney agreement (Ex. 123). The preceding paragraphs are also relevant, if the court is to heed the caveat that it is to give a reasonable mean-

ing so that no part of the contract is surplusage. For clarity's sake, the court will simply recite them. First, paragraphs 17.7 and 17.8 of the Hakky Agreement, which read as follows:

> 17.7 AMS and MEC each represent that their respective current technical disclosures to each other are accurate and complete *with respect to the patent issues in the '779 interference.*
>
> 17.8 AMS and MEC each warrant that there are no other issued patents, nor any pending applications for letters patent, reissue, continuation, continuation-in-part, or divisions *with respect to any device disclosed to the warranting party by the other party which would result in any infringement or other potential litigation issue.*

(Ex. 122 at 24) (emphasis supplied). Also relevant are paragraphs 19.7 and 19.8 of the Finney Agreement, which read:

> 19.7 AMS and MEC each represent that their respective current technical disclosures to each other are accurate and complete *with respect to the patent issues in the '149 Interference.*
>
> 19.8 AMS and MEC each warrant that there are no other issue patents, nor any pending applications for letters patent, reissue, continuation, continuation-in-part, or divisions *with respect to the subject matter of the '149 Interference which would result in any infringement or other potential litigation issue.*

(Ex. 123) (emphasis supplied).[21]

Giving the terms their ordinary meaning, and reading paragraphs 17.8 and 19.8 with their corresponding preceding paragraphs, the court does not find the warranty ambiguous. Paragraph 17.7 requires the "current technical disclosures" to be "accurate and complete with respect to the patent issues in the '779 interference." This is not ambiguous. In light of paragraph 17.7, paragraph 17.8 is not ambiguous either. It is clear to the court that what is meant by "with respect to any device disclosed to the warranting party by the other party" in paragraph 17.8 relates back to the "current technical disclosures" of paragraph 17.7. And the current technical disclosures only had to be "accurate and complete with respect to the patent issues in the '779 interference." In other words, the "warranty" in 17.8 requires the parties to disclose only those patents implicated by the limited "current technical disclosures" referred to paragraph 17.7. The Klatt patent was not required to be disclosed

---

[21] The "'360" Binding Arbitration Agreement contains similar language in paragraphs 23.8 and 23.9. *See* Ex. 124A. However, the "'360" Settlement Agreement (Ex. 124B) states:

> This Agreement specifically supersedes the BINDING ARBITRATION AGREEMENT . . . between the parties and all prior and contemporaneous discussions, understandings or verbal agreements between the parties as they affect the resolution of the present dispute. . . . Neither party shall be bound by any . . . warranty . . . with respect to the resolution of the present dispute other than expressly stated in this Agreement, or as subsequently set forth in writing and executed by a duly authorized officer of the party to be bound by it.

because it does not relate to the interferences.[22] (Tr. 1414-15).

Even if the court were to find that the warranty was ambiguous, the court would reach the same result based on the intent of the parties. Assuming arguendo that the contract was ambiguous, MEC would be entitled to offer extrinsic evidence of the parties' intentions at the time the agreements were executed. *Wisconsin Real Estate Investment Trust v. Weinstein*, 509 F. Supp. 1289, 1295 (E.D. Wis. 1981); *Capital Investment v. Whitehall Packing Co.*, 91 Wis. 2d 178, 280 N.W.2d 254 (1979). However, any ambiguities must be construed in a manner consistent with the agreement's purpose and conducive to the accomplishment of that purpose. *Capital Investment*, 91 Wis. 2d at 189, 191.

The court makes the following findings of fact with respect to the negotiations. AMS and MEC had been developing their respective Hydroflex and Flexi-Flate devices concurrently. AMS had filed and obtained two patents covering different aspects of a particular self-contained inflatable device. MEC, in turn, was a licensee under two patent applications filed by Dr. Said Hakky and Dr. Roy Finney.

In 1982 and 1983, the PTO declared interferences between the AMS patents and the Finney and Hakky patent applications. (Ex. 133- 35; Tr. 1390-91). As often happens, two or more persons may invent substantially the same subject matter at approximately the same time, and file patent applications claiming that subject matter.

---

[22] The same analysis applies to paragraph 19.8.

When that occurs, the PTO must determine who made the invention first, and the first inventor is then entitled to a patent containing claims directed to that invention. The inventions which are the subject matter of the interferences are defined as "counts", and the PTO must determine, for example, who first conceived the invention of the "count," who first reduced it to practice, and what if any, diligence existed. (Tr. 1396-97). Each interference at issue between AMS and MEC had as its subject matter something that was defined and the parties knew what it was. (Tr. 1397). Neither interference involved the subject matter of the Klatt patent in any way. (Tr. 1414-15).

In early 1984, representatives from AMS and MEC met briefly in Puerto Rico. They agreed to discuss the possibility of settling the interferences between the parties. (Tr. 1391). At this time, and throughout the subsequent negotiations, the two companies were direct competitors, and each jealously guarded its proprietary technology. (Tr. 2264-65). However, the fact of the interferences and the desire to settle them required that certain limited technical exchanges be made. (Tr. 2266-67).

On June 14, 1984 the parties met again in the offices of MEC's counsel to discuss the ongoing interferences and whether it would be possible to resolve them short of having one party lose and risk not being able to practice the counts of the interference. (Tr. 1391-92, 1395-96).

On August 30, 1984, the parties met in Minneapolis.[23] (Tr. 1392). They signed a confidentiality agreement governing the exchange by AMS and MEC of "drawings . . . representative of the AMS Hydroflex device and MEC Flexi-Flate device." (Tr. 139-41). This confidentiality agreement was ultimately superseded by the final agreements. (Tr. 1403-04). In order to set the framework of settlement, each party made available to the other certain specific drawings and explained the hydraulic systems employed. (Ex. 143-45; Tr. 1288, 2269, 2396-98). Both parties' drawings showed the penile prosthesis device itself and neither specified whether the devices were prefilled. (Tr. 1398, 2398, 2405, 2412-14). Neither party disclosed to the other—at the August meeting or at any other meeting—a prefilled and sterile product; nor was there a discussion of how the two products would be packaged. (Tr. 1188-90, 1287, 1398-39, 1411-12, 1414-15, 2269-70, 2405). Similarly, no methods of packaging or sterilizing a packaged fluid-containing prosthesis were disclosed by either party at any time (even though both parties had such products generally in mind at the time and both were interested in seeking patent protection on them). (Tr. 1141-4). These matters (prefilling, presterilizing and methods of achieving it), were not exchanged because they were not within the interferences or the patents/applications under discussion. The discussions had limited objectives and, as direct competitors, neither party wanted to disclose unnecessary proprietary information to the other. (Tr. 2411). As of the critical

---

[23] The court found Dr. Christopher Porter's deposition testimony especially helpful and credible with respect to the parties' conduct and intent. (Tr. 2393-2423).

August and December 1984 meetings neither side had a patent application on file regarding a prefilled prosthesis. Indeed, MEC's technical representatives testified that MEC's drawings were left vague on issues that were not squarely encompassed in the then pending interferences. (Tr. 1283-86; see also 2413). Even if it is accepted, as argued by MEC, that the drawings were disclosed to create a settlement broader than the interferences, each party necessarily took the risk of its own nondisclosure because the settlement agreements were specifically based on what was disclosed, not on what might have been disclosed in 20/20 hindsight. (Tr. 2418-23).

MEC asserts that at this meeting, it raised the issue of another patent by Dr. Finney (U.S. Patent No. 4,353,360) and the issue of whether or not the Hydroflex as shown in the drawing infringed it. (Tr. 1287-88; 1399). However, AMS was already aware of the '360 patent (Ex. 147, 138; Tr. 1400-02) and, long before the August meeting had already "scrapped out" its prior version of the Hydroflex in view of the '360 patent. (Tr. 484; 2409-11). Moreover, the '360 patent became an issue because AMS' technical disclosure implicated it. By contrast, nothing MEC chose to disclose to AMS ever implicated the Klatt patent in suit.

The parties convened again in December 1984 to continue their negotiations to settle the existing disputes. (Ex. 150-58; Tr. 1393-95, 1405). At some point during negotiations, MEC raised the existence of a reissue application. At the time of the settlement discussions, MEC was attempting to present claims by reissue that would be placed in interference with one or more of the patents that were already involved in one of the then pending in-

terferences between the parties. This reissue application thus was directly related to one of the interferences and was ultimately incorporated into the agreements. (Tr. 1405-06). All AMS received from MEC regarding the reissue was information available to the public. (Tr. 1406-07). Again, the reissue application arose from matters actually in controversy, something which did not occur regarding Klatt.

Thereafter, the parties continued to negotiate the agreements necessary to settle all the pending disputes. (Tr. 1393-94). Drafts of agreements were prepared, and those drafts were carefully studied and revised by all parties. (Ex. 150-58; Tr. 1403, 1409-11). The individuals involved on behalf of MEC in this matter included Dave Sanders (president of MEC), Garry Carter (chief technical officer of MEC), Robert Wiles (CEO of MEC), and four sets of patent and general attorneys. The attorneys consisted of Thad Kryshak of Quarles & Brady, and in-house patent counsel from Bristol Meyers and sister corporation Zimmer, Inc. (Tr. 1195). MEC was fully involved in the drafting of the terms of the settlement agreements. (Tr. 1403, 1411).

Ultimately, in March and April 1985 the parties executed three separate agreements settling, respectively, the Hakky-AMS interference (Ex. 122), the Finney-AMS interference (Ex. 123), and providing for arbitration of the '360 patent (Ex. 124A). The Hakky-AMS interference settlement also included Dr. Hakky as a party to the agreement. (Tr. 1394-95). Each agreement contained a specific integration clause which was understood by Mr. Wiles when he signed the agreements. (Tr. 1191-92, 1403). MEC knew full well that any alleged prior under-

standing or promise, whether written or oral, was extinguished by the final settlement agreements.

In general terms, the two interferences were settled by agreements that the PTO would decide who had priority of the inventions. However, the winning party would automatically licenses the losing party under any issued patent. Therefore, both parties were protected, no matter who won the interference.

With respect to the '360 patent, the parties agreed to arbitrate the question whether AMS' disclosed Hydroflex device fell with the scope of the '360 patent claims, by submitting the issue to a neutral third party. Again, the parties agreed that the winning party would license the patent to the losing party.

With respect to the above '360 patent Binding Arbitration Agreement, the parties began the process of arbitration, and chose an arbitrator. Thereafter, AMS and MEC agreed to resolve the matter outside of arbitration. To mollify Dr. Finney, who had a license agreement with MEC under the '360 patent, the two companies each paid Dr. Finney $ 50,000 in return for MEC granting AMS a nonexclusive, paid up license under the '360 patent to make, use and sell the Hydroflex device. (Ex. 124B).

The court concludes on these findings of fact that MEC's claim that the intent of the agreements was broader than the agreements executed by the parties ignores the circumstances of the negotiations and common business realities. AMS and MEC were direct competitors in the highly competitive penile prosthesis market. They were not likely to disclose to each other their trade secrets, confidential business information, future product

improvements or intentions without a clear motivation and a plainly worded agreement. There is no evidence of any agreement that the disclosures be any more broad than that which is explicitly stated. (Tr. 2406). These competent and represented business persons would not agree to "disclosures" without clearly and explicitly defining their parameters. Both sides clearly disclosed only as much as was necessary to settle the issues at hand.

Next, the court turns to the balance of MEC's counterclaims. MEC's third counterclaim alleges that the nondisclosure of Klatt is intentional misrepresentation; the fourth counterclaim alleges negligent misrepresentation; and the fifth counterclaim alleges fraudulent misrepresentation. Each of these causes of action shares three common elements: 1) that the representation must be of fact and made by the defendant; 2) the representation of fact must be untrue; and 3) plaintiff must believe such representation to be true and rely thereon to his damage. *Whipp v. Iverson*, 43 Wis. 2d 166, 170, 168 N.W.2d 201, 203 (1969).

MEC stated in paragraph 36 of its proposed conclusions of law that:

> A warranty can constitute a misrepresentation and therefore be the basis of an action for false representation. See 93 C.J.S., *Warranty*, section 42. Even though fraud and breach of warranty claims can be "virtually impossible to distinguish . . .," a plaintiff in Wisconsin is entitled to a separate judgment for each claim. *Eklund v. Koenig & Assocs., Inc.*, 153 Wis. 2d 374, 378 (Wis. Ct. App. 1989).

The court has no reason to discount this authority. Nevertheless, the court finds that there was no misrepresentation of fact. Simply because the warranty represents that "there are no patents pending" does not make AMS' failure to reveal Klatt a misrepresentation. As discussed above, Klatt was not within the scope of the interferences and consequently was not required to be revealed in order to comply with the warranty. AMS had no duty to disclose Klatt. *Whipp*, 43 Wis. 2d at 170, 168 N.W.2d at 203. Also, there is no evidence in the record to suggest that AMS represented that it had no plans to prefill its prosthesis. Indeed, there is no persuasive evidence to suggest that this was even a topic for discussion. (Tr. 2406).

MEC also claims AMS is equitably estopped from asserting infringement. The court rejects this assertion outright because there has been no express misrepresentation.

Finally, MEC claims that it has an implied license to use the Klatt patent for the period of time after Klatt issued and before MEC switched to the vacuum pack. MEC states that, under the settlement agreements, it has a license to make, use and sell penile prosthesis under another AMS patent, U.S. Patent Number 4,383,525. MEC says that, according to AMS, defendant would have been unable to package and sell devices manufactured under the claims of that AMS patent because such a sale would infringe the claims of the Klatt patent in suit, also assigned to plaintiff. Thus, MEC contends that

> an implied license arises where, as here, a party sells a product or licenses a patent (the '525

> patent) that cannot be used (according to AMS) as intended, unless a license is implied under another patent or patents (the Klatt patent) owned by the same party.

MEC's proposed conclusions of law, paragraph 43.

The court rejects MEC's argument that is would be unable to practice the '525 patent unless it has an implied license for Klatt. As MEC has demonstrated with its own vacuum pack, there were other methods of transporting a penile prosthesis to the operating room in a prefilled and sterile condition.

X. Summary

The court has found the Klatt patent not invalid for obviousness. The patent is valid and was infringed. The court rejects MEC's counterclaims in their entirety. AMS is entitled to lost profits for the period October 1987 to December 1987 in the amount of $906,806.00 AMS is entitled to a reasonable royalty for the period January 1988 to December 1988 in the amount of $46,264.24, resulting in total damages of $953,070.24. AMS is entitled to a willfulness multiplier of 1.5 on its compensatory damages, resulting in $1,429,605.30 in total damages.

AMS shall submit a proposed judgment and memorandum related to its request for prejudgment interest within 30 days of today's date. MEC shall submit any objections to the proposed judgment, as well as any response to AMS' request for prejudgment interest within 20 days after receipt of AMS' submissions.

Dated at Milwaukee, Wisconsin this 25th day of June, 1992.

No. 92-1538

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

AMERICAN MEDICAL SYSTEMS, INC.,

Plaintiff/Cross-Appellant,

v.

MEDICAL ENGINEERING CORPORATION,

Defendant-Appellant.

December 6, 1993

ORDER:

A combined petition for rehearing and suggestion for regearing in banc having been filed by the APPELLANT, and a response thereto having been invited by the court and filed by the CROSS-APPELLANT, and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the suggestion for rehearing in banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the suggestion for rehearing in banc be, and the same hereby is, DECLINED.

The mandate of the court will issue on December 13, 1993.

Circuit Judge ARCHER did not participate in the vote.